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ABSTRACT

The first five-year research plans developed by the National Institute of Child Health and Human Development (NICHD), covering fiscal years 1983-1987 and 10 program areas, are published in this volume. Present knowledge is reviewed and research opportunities are indicated in the areas of reproduction, fetal development, the birth process, the newborn, infancy and childhood, adolescents, and family and populations. Subsequently, priorities for future research are specified for the 10 program areas of (1) fertility and infertility, (2) pregnancy, birth and the infant, (3) nutrition, (4) sudden infant death syndrome, (5) congenital defects, (6) mental retardation, (7) child and adolescent development, (8) contraceptive development, (9) contraceptive evaluation, and (10) population dynamics. The volume also contains a description of a strategy for annual program evaluation and further planning. Appendices provide a description of the method of study used by the NICHD Steering Committee, a description of the task with which the study groups were charged, an outline of the review process and a listing of reviewers, and the procedure used to arrive at the research plan. (Author/RH)

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Child Health and Human Development

An Overview and Strategy for a Five-Year Research Plan

Prepared at the direction of the Steering Committee for the Five-Year Research Plan, National Institute of Child Health and Human Development

PS012239

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
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May 14, 1981

Norman Kretchmer, M.D., Ph.D.
Director
National Institute of Child Health
and Human Development
National Institutes of Health
Bethesda, Maryland 20205

Dear Doctor Kretchmer:

On behalf of the Steering Committee, I am pleased to transmit this Five-Year Research Plan for the National Institute of Child Health and Human Development pursuant to your charge of May 23, 1979. You directed the Committee to design a process for developing a research plan that would encompass both the intramural and extramural activities of the Institute. The Committee's findings and recommendations are presented in these volumes.

The Committee's work was based on evaluation of the Institute's 10 areas of research emphasis. Over the course of 18 months, and with the able assistance of the Institute's program staff, the Committee developed a Plan that includes research objectives for the first year and a strategy for continuing evaluation and planning in subsequent years.

These two volumes should make clear the need for sustained vigorous pursuit of the knowledge needed to assure all children the opportunity to fulfill their potential for healthy and productive adult life.

We hope that our report will be of value to the Institute and, especially, to our nation's mothers, children, and families.

In transmitting these volumes, the Steering Committee wishes to acknowledge the contributions of the many consultants in the biomedical and behavioral research community and the staff of the Institute who developed the Plan.

Respectfully,

Robert H. Alway

Robert H. Alway, M.D.
Chairman, Steering Committee
NICHD Five-Year Research Plan

Preface

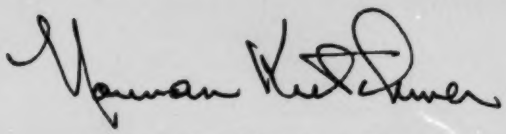
As Director of the National Institute of Child Health and Human Development, I have been deeply concerned about the future of knowledge-building activities in this country. Within the past decade, and concurrent with greater fiscal constraints on the Federal budget, we have seen greater public awareness of research and its results. We are confronted with a new set of pressures and demands. Specifically, I refer to those events that have affected the climate in which research is conducted. A new public demand for accountability is evidenced by the creation of public panels and commissions to assess the implications of new technologies in medical research and the establishment of major initiatives for health-research planning. As the Institute enters its third decade, it is vital that we look critically at our present activities and plan for our future.

We have made great progress in expanding knowledge on human development. Human genetics has been transformed into a discipline of tremendous exploratory power. Recent advances in cell culture, somatic cell hybridization, and recombinant DNA methodology suggest that we may be entering an era in which the DNA base sequence can provide an approach to new methods for therapeutic intervention and treatment. In endocrinology, the discovery and purification of hormone receptors and their relationship to growth and development have opened a whole new area of exploration. In perinatology, techniques of biochemistry have been applied to the prevention of respiratory distress syndrome and insights of behavioral science to the problem of providing adequate stimulation for premature infants. We must remember, however, that there is a great deal that we do not yet know. For instance, prematurity is still a major problem and its sequelae are not fully predictable. Every year thousands upon thousands of children die or are crippled by disorders that we have neither the knowledge to treat nor the wisdom to prevent.

We must acquire this knowledge. Promoting its growth, along with promoting health, remains the primary mission of the National Institute of Child Health and Human Development. Of all the Federal agencies, this Institute is the only one that is focused primarily upon research on the reproductive, physiological, and behavioral processes that determine the health of children, adults, families, and populations. To pursue our mission effectively, we must plan for and identify those questions and problems that are ready for scientific exploration.

It was in this spirit that I established the Steering Committee for the NICHD Five-Year Research Plan and asked it to develop a sound rationale to justify future directions and new programs in maternal and child health and in population research.

It is my hope that the Plan that evolves from the Steering Committee's work will not only provide a framework to guide the Institute's efforts in the coming years but will also serve the National Advisory Child Health and Human Development Council and other stewards of this health-research enterprise in assuring effective and responsible expenditure of public funds.



Norman Kretchmer, M.D., Ph.D.
June 5, 1981

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Foreword

In May of 1979, the Director of the National Institute of Child Health and Human Development (NICHD) established a Steering Committee for a Five-Year Research Plan and asked the Committee to provide "a sound rationale to justify future directions and new programs in maternal and child health and in population research."

Study Groups, consisting of outstanding biomedical and behavioral scientists from the nation's research community and members of the Institute's extramural and intramural staff, were appointed for each of the 10 NICHD program areas. The Study Groups were formally charged in February 1980 with responsibility to evaluate the state of the science, to identify areas of promise, and to recommend directions for future research.

Beginning in July of 1980, the Steering Committee conducted an extensive examination involving scientific and policy review of each of the Study Group reports. These reports, with the benefit of review and comment by peers, are published in the companion volume Child Health and Human Development: An Evaluation and Assessment of the State of the Science (NIH Publication No. 82-2304).

After the reviews, the Steering Committee developed a research plan based on the Study Group recommendations and program staff assessments and established a procedure for annual evaluation and planning. The evaluation and planning procedure enables the Institute to monitor its research progress and to address, on a continuing basis, the full breadth of research needs within each program area.

Research plans for Fiscal Year 1983 for each of the 10 program areas are published in this volume, which also contains a description of the evaluation and planning strategy and a section on the status of research related to developmental and health problems.

The appendices contain a description of the method of study used by the Steering Committee, the charge to the Study Groups, the review process and reviewers, and the procedure used to arrive at the Research Plan.

The National Institute of Child Health and Human Development: The First 20 Years

Background

In 1960, President John F. Kennedy's Task Force on Health and Social Security recommended the establishment of a child health institute that would focus on the normal processes of human maturation. Appropriate agency officials and representatives of the scientific community were consulted on existing Federal programs in child health and development and possible new programs. Congressional hearings on the proposed institute were held early in 1962.

The bill that evolved was signed into law on October 17, 1962. It authorized the National Institute of Child Health and Human Development (NICHD) to conduct and support research and training "relating to maternal health, child health, and human development, including research and training in the special health problems and requirements of mothers and children and in the basic sciences relating to the processes of human growth and development, including prenatal development."

The Institute was officially established on June 30, 1963. The research it supported was divided into four areas: reproduction, growth and development, aging, and mental retardation. In 1968, population research was given added importance and impetus when the Center for Population Research was established within the NICHD by the Secretary of Health, Education, and Welfare and was designated by the President as the lead agency for population research and training for the Federal government.

Several changes were made in 1975. The NICHD Center for Research for Mothers and Children was established by the Secretary of Health, Education, and Welfare to provide a national focus for research and research training in the

health problems of mothers and children, with responsibility for increasing knowledge about pregnancy, infancy, childhood, and adulthood. In addition, the research program on aging was transferred from the NICHD to the newly established National Institute on Aging.

In response to these changes, the Institute and the National Advisory Child Health and Human Development Council decided that it was important to review the Institute's research programs. The Planning and Evaluation Subcommittee of the Council analyzed the NICHD research program and identified 10 emphasis areas to be used as the basis for subsequent review and planning. These 10 areas are: Fertility and Infertility; Pregnancy, Birth, and the Infant; Nutrition; Sudden Infant Death Syndrome; Congenital Defects; Mental Retardation; Child and Adolescent Development; Contraceptive Development; Contraceptive Evaluation; and Population Dynamics. Experience over the past 6 years has shown that these areas provide an effective framework for the planning, development, and evaluation of the Institute's programs.

Mission

The Institute has broad responsibility for research on problems of growth and development. In the United States about two-thirds of all deaths of newborns are linked to low birthweight and prematurity, and the infant death rate is higher than that of 13 other countries in the world. Each year, hospital costs for intensive care of premature infants exceed 1.5 billion dollars. Of every 1,000 live births, 70 infants enter the world with mental or physical defects; the causes of 65 to 70 percent of these defects remain unknown. Adolescent pregnancy is an issue of continuing concern. Although declines in the adolescent birth rate have recently been recorded, the rates are still high among very young adolescents, who are also most likely to have complications of childbearing and childrearing. Many pregnancies are unwanted, and, conversely, many couples who want children are unable to have them.

To approach solutions to these and similar health issues, the NICHD has based its programs on the concept that adult health and well-being are determined in part by episodes early in life, that physical and mental change is continuous throughout life, and that reproductive processes and the management of fertility are of major concern not only to the individual but to society. The Institute's goal is to assure the means of improving health and well-being through advances in knowledge of human reproduction, growth, development, and maturation. Nationally and within its own facilities, the NICHD conducts and administers a program of clinical and fundamental research and research

training, encourages and assists in the transfer of findings to practice, and disseminates information about research advances in child health and human development to scientists, health practitioners, and the public.

Organization

The Institute is organized into four units: the Center for Research for Mothers and Children and the Center for Population Research, which support extramural research through grants and contracts to universities, medical schools, and similar institutions across the country; the Intramural Research Program, which is conducted in the Institute's laboratories and clinics in Bethesda, Maryland; and the Epidemiology and Biometry Research Program, which provides biostatistical, epidemiological, and computer science resources.

During the 1960s, the Institute began supporting Mental Retardation Centers in facilities constructed at universities and research hospitals throughout the country under legislation passed by the Congress in 1963. The Centers conduct research on the biomedical and behavioral origins of mental retardation and on its prevention and amelioration. The Institute initiated the Population Research Centers program in 1968. The program supports research on reproductive biology and endocrinology and on social and behavioral factors in population sciences. In 1976, the NICHD began the process of establishing seven Major Research Programs in order to stimulate research in perinatal medicine and to facilitate the transfer of new scientific knowledge into health-care delivery. The purpose of the Major Research Programs, which was endorsed by the House and Senate Appropriations Committees, is to coordinate biomedical and behavioral research directed toward infant survival. Each Major Research Program encompasses a specific unresolved problem or need in perinatology: four are concerned with maternal diabetes, one with premature labor, one with sudden infant death syndrome, and one with fetal hypoxia.

For Fiscal Year 1981, the Institute's estimated obligations were $107,285,000 for research for mothers and children; $78,524,000 for population research; $23,377,000 for intramural research, including about $900,000 for epidemiology and biometry research; and $11,442,000 for program administration. The total budget was $220,628,000.

Figure 1 shows the growth of the NICHD budget since 1964 according to program areas. Figures 2 and 3 show the budget histories of recent years by funding mechanism and on the basis of activity. An analysis of NICHD extramural expenditures in 1980 is shown in figure 4.

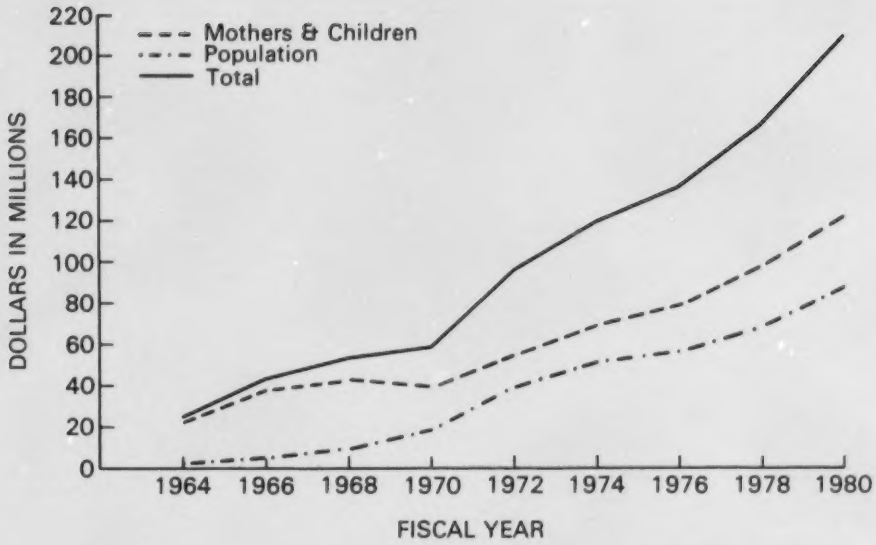

FIGURE 1. GROWTH OF THE BUDGET AND MAJOR PROGRAMS

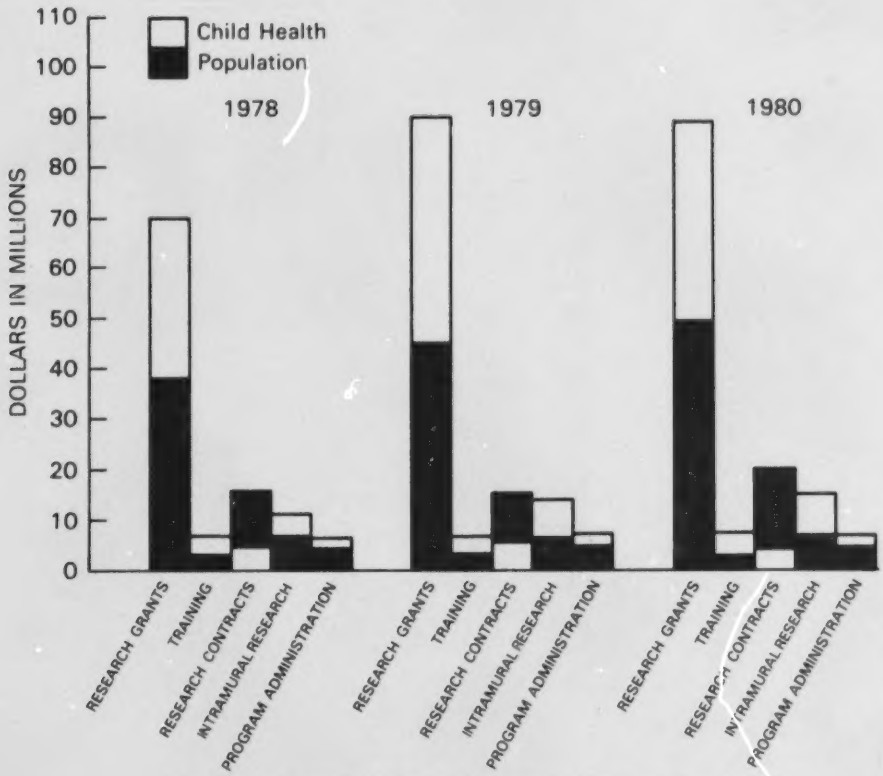

FIGURE 2. ANALYSIS OF THE BUDGET BY FUNDING MECHANISMS FISCAL YEAR 1978 - 1980

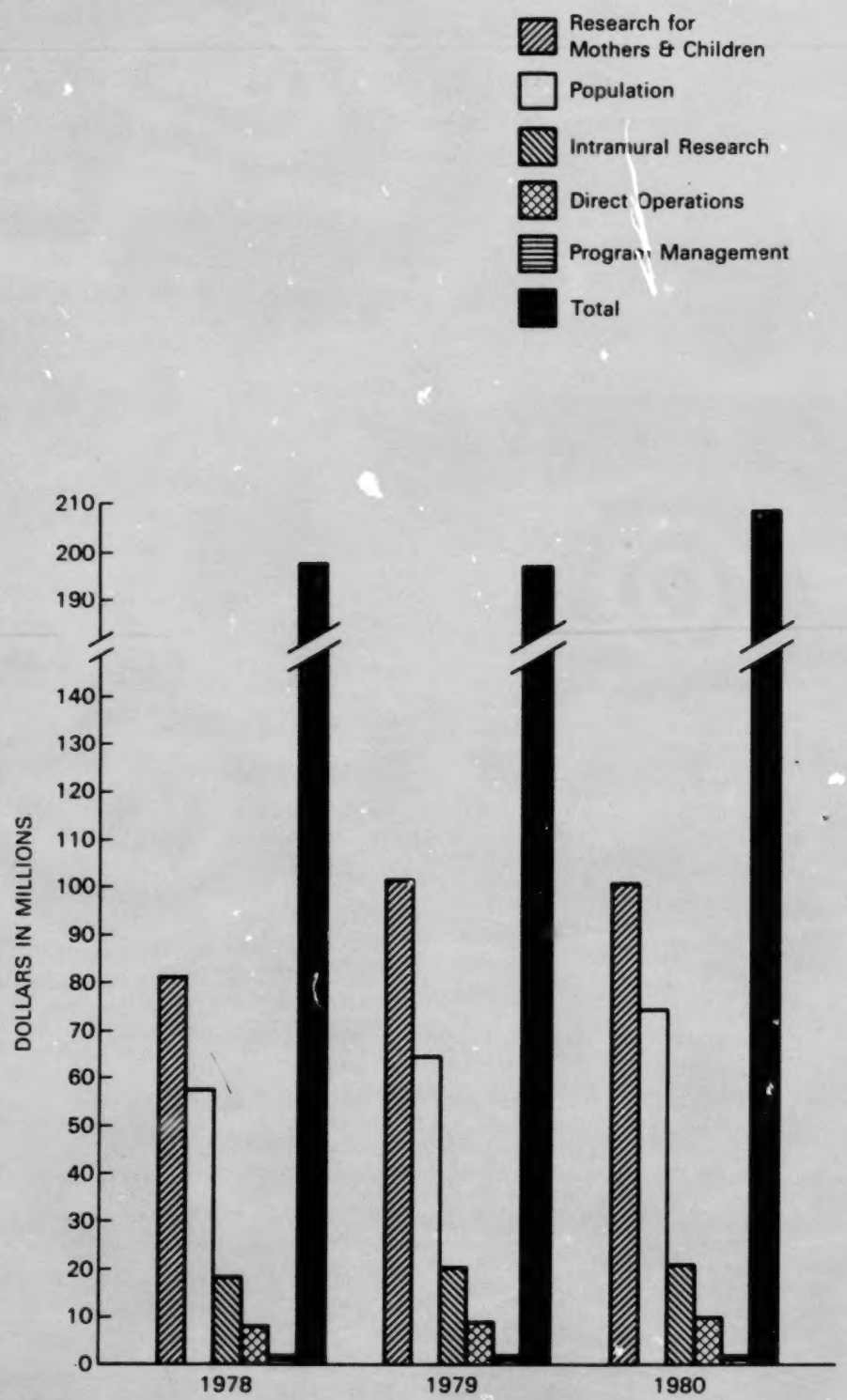

FIGURE 3. BUDGET HISTORY BY ACTIVITY

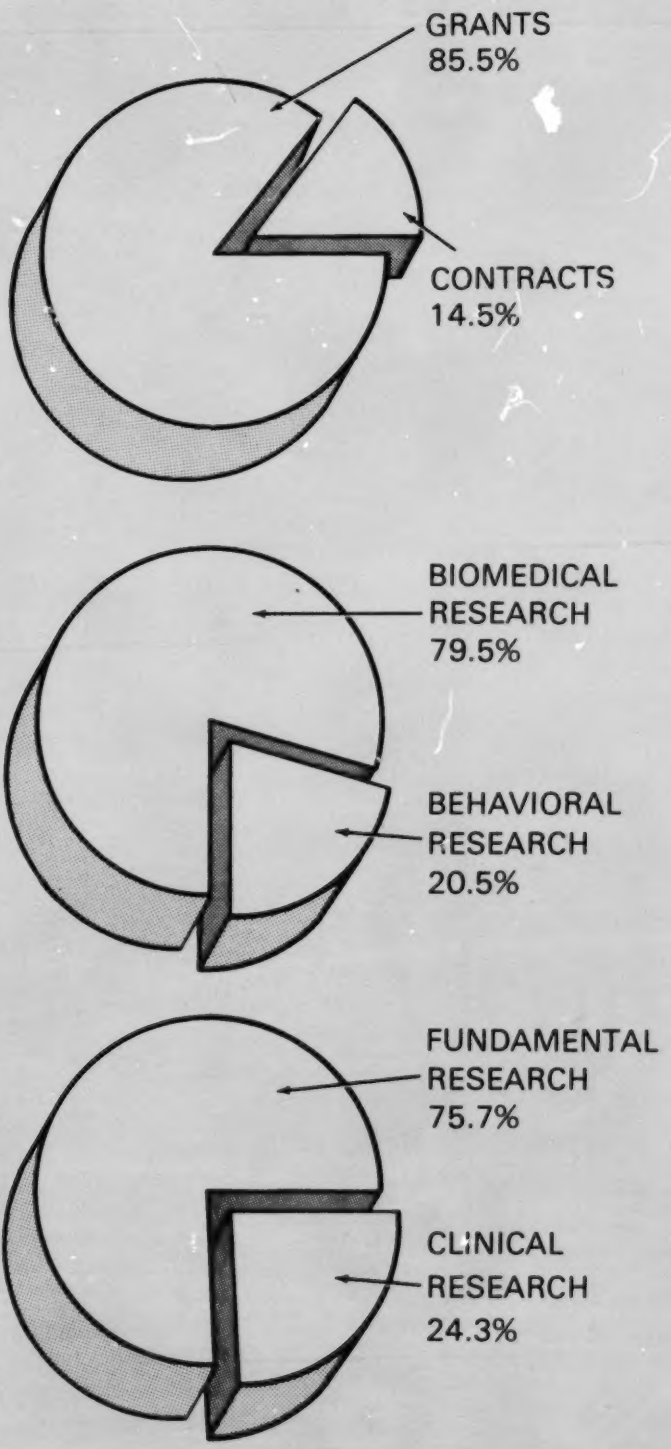

FIGURE 4. NICHD EXTRAMURAL SUPPORT IN 1980

Responsibilities

The mission of the NICHD gives the Institute the major Federal responsibility for research on child and maternal health. In that capacity, and with other Federal agencies and voluntary and professional organizations, the Institute maintains an awareness of ongoing activities, facilitates the exchange of information and ideas, stimulates research, and encourages the translation of new knowledge into prevention and health-care activities. The Director of the NICHD Center for Population Research, for example, chairs the Interagency Committee on Population Research, which was established in 1970 to coordinate Federal population research programs.

The Institute participates in the interdepartmental Adolescent Pregnancy Programs Coordinating Committee, which has a membership of 11 agencies, including the Administration for Children, Youth, and Families; the Alcohol, Drug Abuse, and Mental Health Administration; and the Bureau of Community Health Services. The NICHD is an active participant in the activities of the National Institutes of Health (NIH) Nutrition Coordinating Committee, and, in cooperation with the U.S. Department of Agriculture (USDA), participates in coordinating USDA-supported nutrition research centers.

By sponsoring conferences and workshops, the NICHD brings together scientists from the United States and other countries to review the state of the science in various areas and to make recommendations for future research. The "Workshop on Natural Family Planning," for example, was convened in June 1979 by the NICHD, the Bureau of Community Health Services, and the World Health Organization. The 65 participants in the conference emphasized the efficacy of natural family planning (NFP) methods and recommended more research on socio-behavioral aspects of these methods. "A Conference on Women: A Developmental Perspective" was sponsored in 1980 by the NICHD in cooperation with the National Institute of Mental Health and the National Institute on Aging.

In conjunction with the National Center for Health Care Technology and the NIH Office for Medical Applications of Research, the NICHD sponsored a consensus development conference in 1980 on issues related to cesarean childbirth. A similar conference was held in the previous year to assess the status of techniques used in antenatal diagnosis.

Five-Year Research Plan

This first Five-Year Research Plan for the National Institute of Child Health and Human Development, covering

Fiscal Years 1983-1987, is the result of the Institute's interest in developing a rationale for long-term program directions and emphases. Because of the recent trend toward limited research resources and increasing inflationary pressures on purchasing power, and because of the growing complexity of the Institute's programs, long-range planning is of major importance. The NICHD is committed to a strategy of evaluation and planning as the most effective means to use resources well, to establish research priorities, and to develop a basis for accountability of public funds in its charge.

As the NICHD approaches its 20th year of research activity and looks toward its quarter-century anniversary, the Five-Year Research Plan, updated each year, will provide a continuing strategy for progress toward the Institute's goals.

Research Status and Opportunities

Human development is a progression of delicately balanced biological and behavioral processes and events. Under normal circumstances, the progression is smooth and orderly. When development is defective or the progression disrupted, an abnormality may result. During the 20 years of the existence of the NICHD, the knowledge needed to assure normal development and to prevent, detect, and treat abnormalities has been expanded significantly, but it is still limited. Research on what remains to be learned about these processes is the heart of the NICHD program.

Reproduction

Reproductive biology is the study of the transmission of life. Few areas of biology have a greater impact on individuals and on society. The control of sexual differentiation and development, the promotion of reproductive health, the provision of adequate and safe methods of fertility regulation, the alleviation of infertility, and the treatment of reproductive diseases rest upon a better understanding of the mechanisms involved in the reproductive processes.

Fertilization, Implantation, and Differentiation. Fertilization is the normal result of the union of maternal and paternal chromosomes from an egg and a sperm. Before fertilization, the mature egg is released from the ovary and transported into a fallopian tube of the uterus. Spermatozoa (sperm cells) do not attain their full capacity for fertilization until after they enter the female reproductive tract, where they undergo physiological changes that enable them to penetrate the outer membrane of an egg. This final preparation of the sperm for fertilization is called capacitation.

Advances in cell biology and techniques of embryo culture have contributed to an increased understanding of the

early stages of development. The fertilized egg contains all the genetic information necessary for growth and development. The molecular events in the zygote that allow interactions between maternal and paternal DNA promote cell division, motion, and differentiation, and result in formation of a multicellular organism from the single cell. The maternal and paternal chromosomes combine to form a diploid cell, which contains the diploid number (46) of chromosomes characteristic of the somatic, or body, cells of man. Early events, such as closure of the membrane of the egg after the sperm has passed through it, depend on processes in the ovum. By the time the fertilized egg has developed into an 8-cell zygote, however, the formation of certain enzymes (embryonic proteins) permits the embryo to express its own genes, which, in turn, determine cellular differentiation.

The fertilized egg has no means of self-propulsion; the fallopian tube provides the mechanisms for transport into the uterus. At present, a detailed understanding of the control and integration of the transport mechanisms is lacking, and such an understanding is needed because disordered tubal transport is one factor in human infertility. Failure of the zygote to move into the uterus by the time of implantation results in an ectopic pregnancy, which, with rare exceptions, terminates in the destruction of the embryo and may threaten the life of the mother.

Infertility and Other Reproductive Disorders. Infertility affects an estimated 15 percent of couples. One cause of infertility in women is the absence or infrequency of ovulation. Another is endometriosis, a disease characterized by the presence of endometrial tissue other than at its normal location, the lining of the uterus. In men, infertility is caused by a wide variety of problems, including a hormonal deficiency that results in an inadequate number of sperm. NICHD-supported research on hormones has resulted in successful methods of treatment for this deficiency.

The administration of human gonadotropins is successful in stimulating ovulation in women and in producing adequate numbers of sperm in men, and long-term treatment of many women with the hormone progesterone has eased the pain and alleviated the infertility associated with endometriosis. Additional knowledge about hormonal processes may increase the number of treatable disorders of this kind.

Other causes of infertility are suspected. In the female, primitive egg cells that are destined to become eggs appear soon after the formation of the embryo. The initial number of about 1,700 primitive eggs increases to about 600,000 during the 6th through 8th weeks, and to almost 7 million by the 20th week. Through a process of elimination known as atresia, the population of about 7 million eggs is reduced to 1 to 2 million by the time of birth and to about

400,000 by the time menstruation and ovulation begin. Knowledge about the control of this maturation process and how primitive eggs may be selected for ovulation while the remaining ones succumb to atresia may permit the development of other measures for the alleviation of infertility.

Contraception. Research supported by the NICHD has also led to new knowledge about methods of contraception. Although a variety of contraceptive methods are in use, there are still many problems associated with their effectiveness, safety, acceptability, and convenience.

During the past 5 years, the use of contraceptive pills has declined in the United States, in large part because of concerns about adverse effects on health. Although fatal heart attacks are infrequent in women of reproductive age, reports have revealed a threefold increase in the risk of both fatal and nonfatal heart attacks among current users of the pill, and this risk is even greater in those who smoke. Results of other studies have shown that the use of the pill causes a slight increase in blood pressure, which is reversed when the pill is discontinued. Other studies offer evidence that the combination of hypertension, oral contraceptives, and smoking increases the risk of stroke.

Most data to date show that oral contraceptive users have no significantly excessive risk of developing breast cancer, nor has a relation between oral contraceptives and cervical cancer been demonstrated with certainty. In fact, oral contraceptives may protect women from uterine and ovarian cancer.

The incidence of some medical conditions--urinary tract infections, gallbladder disease, and certain liver disorders--is increased in women who use oral contraceptives. Conversely, it has been found that these women have less iron-deficiency anemia, fewer benign breast cysts, and fewer ovarian cysts; some have fewer menstrual problems. The risk of thromboembolic disease (blood clots in veins) associated with oral contraceptives was substantially reduced by the introduction of preparations containing less estrogen and less progestin.

New knowledge about human reproduction and hormonal interrelations and interactions could lead to even greater improvements in oral contraceptives. During the past decade, NICHD investigators have contributed to the synthesis of new classes of contraceptive drugs. Some of the drugs have sufficient potency to warrant full-scale toxicological assessment and initial clinical trials.

NICHD-supported research on the efficacy and safety of contraceptive drugs also involves studies on new and improved

methods of administering them. Recent approaches have included the subcutaneous implantation of devices that serve as reservoirs for the release of contraceptives by diffusion.

Barrier methods, such as the diaphragm and condom, are of interest because of their simplicity and relative safety. Research is also being directed toward new materials for diaphragms, such as sponges, and toward improved spermicide formulations. During the past few years, investigators have renewed their interest in the cervical cap, which may be used with or without a spermicide. At this time, however, the data are limited, and the cervical cap is therefore classified as an experimental device. NICHD-supported clinical trials are now under way.

Studies supported by the Institute have shown an association between the use of IUDs and pelvic inflammatory disease, particularly among young women who have never been pregnant. Although not usually life threatening, pelvic infection may cause infertility.

Another method of contraception is sterilization, which involves blocking the passage of either sperm or eggs. Because reliable techniques for reversing sterilization have not yet been perfected, the option of sterilization poses problems for both men and women. Moreover, one-half to two-thirds of vasectomized men develop circulating antibodies to sperm antigens, but no clinical consequences have yet been associated with this finding. In studies of nonhuman primates, there was an increase in the incidence of atherosclerosis 9 to 14 years after sterilization by vasectomy, and this important observation is now being followed up by detailed studies in humans.

At the theoretical level, biological regulators of reproductive function have been identified in the ovaries and testes, and they appear to be promising candidates for contraceptive agents. A second approach being explored at the theoretical level is the immunological management of fertility. The finding that both female and male laboratory animals can be made infertile by immunological means has stimulated basic research to develop antifertility vaccines.

Fetal Development

In humans, the embryo is formed shortly after implantation during the 2nd week after fertilization. The first 2 months represent the period of embryogenesis, when organs are formed. The fetal period begins at about 8 to 9 weeks of gestational age and extends to birth.

Genetic sex is determined at fertilization, when the X (female)-bearing egg fuses with an X- or Y (male)-bearing sperm. In the male, differentiation of the gonads and genital organs requires a series of interdependent genetic, endocrinological, and biochemical events that begin at about the 7th week of pregnancy, when the primitive gonads evolve into testes. By the 8th week, the testes consist of cords of germ cells and other cell precursors that will form tubules and interstitial cells that secrete the male sex hormone. Even the embryonic testes are hormonally active; their secretion triggers the regression of the müllerian ducts, which, in the absence of a male sex hormone, would form fallopian tubes and a uterus. The embryonic testes also secrete the testicular hormone, testosterone, which stimulates the wolffian ducts to form the other male genital organs.

During fetal brain development, nerve cells differentiate, organize into different systems, and make appropriate functional connections with other nerve cells, sensory organs, and muscles. Proliferation and migration of nerve cells are usually major events during the first half of pregnancy; the process of brain development, however, continues after the fetal period and into the second decade of life.

The complexity of the "genetic program" that directs human differentiation has been estimated as equivalent to 10 million printed pages. It is therefore not surprising that development may go awry as a result of errors either in the internal genetic program or in response to external factors. The effects may range from lethal fetal defects, resulting in spontaneous elimination from the mother's uterus, to mild physical or mental impairment of the child.

Congenital Defects. A disruption in cellular differentiation or in the developmental process can cause a congenital defect, which can be a structural, functional, or biochemical abnormality. Congenital defects are a major cause of mortality among newborns and are also responsible for about 50 percent of miscarriages that occur early in pregnancy. The prevalence of congenital defects has led to extensive research supported by the NICHD on their prevention and correction.

Congenital defects have been defined according to two general categories: abnormalities that have an hereditary basis and those that are caused by nonhereditary factors such as environmental insults. Abnormalities that have an hereditary basis may involve a single gene, multiple genes, or chromosomal aberrations. Phenylketonuria (PKU), an inherited metabolic disease associated with a deficiency of the enzyme phenylalanine hydroxylase, can result in brain damage and neurologic abnormalities, with subsequent severe mental retardation. Cystic fibrosis is also hereditary, but its

underlying metabolic defect is still unknown. Down syndrome is the result of chromosomal aberrations; it is characterized by mental retardation and physical abnormalities. The risk of Down syndrome increases as maternal age increases, and there is recent evidence that paternal age may also play a role.

Research has led to progress in correcting metabolic defects of the fetus. An understanding of biochemical metabolism often permits the development of a treatment. For example, a midterm fetus was found to have a biochemical defect called methylmalonic acidemia, a condition that can result in mental retardation or early death. Treatment of the mother with large doses of vitamin B_{12} during the last 9 weeks of pregnancy, along with postnatal treatment of the child, corrected the defect and prevented death from acidosis as well as mental retardation. As another example, aberrations of sexual differentiation are known to result from a defect of synthesis of adrenalsteroid hormones during pregnancy. The defects have been corrected in experimental animal models by replacement of missing hormones at appropriate critical embryonic periods.

Research progress in understanding genetically caused abnormalities has been impressive. The biochemistry of some inherited diseases has been defined, and treatment and prevention are possible in many cases. The etiology of 65 to 70 percent of congenital defects is still unknown, however, and the NICHD is continuing to identify specific teratogenic causes. Increased understanding of the molecular basis of chromosomal defects may permit effective intervention through promising new gene-splicing techniques based on recombinant DNA technology.

Environmental Hazards. Advances have also been made in understanding environmental factors that may lead to congenital defects and other problems during fetal development. These factors include prenatal exposure to maternal infection, maternal metabolic imbalances, drugs, deficient nutrition, and environmental chemicals and toxins.

Human cytomegalovirus (CMV) infection, which is transmitted by the mother to the infant prenatally or during the birth process, is a common infectious cause of congenital mental retardation and deafness. Other possible long-term problems that may be the result of CMV infection, such as learning disorders, are the subject of current studies. Vaccines for the prevention of CMV infection are being tested, but they are still in experimental stages.

Thyroid disease and diabetes are other maternal diseases that may increase the incidence of congenital defects. Congenital hypothyroidism, which can lead to mental retarda-

tion, may occur in the offspring of mothers with goiter. In the pregnant diabetic, hyperglycemia--abnormally high concentration of glucose in the circulating blood--may be the cause of defective fetal development. Improved prenatal care, however, has reduced the mortality rate for infants of of diabetic mothers, and may reduce the incidence of congenital defects as well.

Maternal Nutrition. Adequate maternal nutrition is crucial during prenatal development. Results of research on the nutritional relation between the mother and the fetus and its effect on fetal development have shown that the utilization of specific nutrients is altered to meet the nutritional requirements associated with pregnancy. For example, iron absorption increases; at the same time, excretory loss is reduced because the pregnant woman is not menstruating. In an attempt to prevent iron deficiency, some clinics routinely treat all pregnant women with daily supplemental iron. Results of a recent British study, however, provide preliminary evidence that supplemental iron may pose a risk to the iron-sufficient, healthy pregnant woman and fetus.

Studies supported by the NICHD have shown that the placenta is the essential organ for adjusting maternal provision of nutrients to assure adequate fetal support. In addition to controlling the rate and selection of nutrient transfer, the placenta synthesizes and secretes hormones that modify maternal metabolism. The hormone human placental lactogen appears to assure a constant supply of maternal glucose to the fetus. As a means of sparing glucose for the fetus, maternal fatty acids are mobilized as the predominant oxidative fuel for the mother. Human placental lactogen may also increase the fetal supply of amino acids, through restriction of maternal utilization of proteins in late gestation.

Despite all that has been learned, the effect of subtle dietary deficiencies during pregnancy is still not clear. Information is also needed on diets for pregnant women with metabolic disorders.

Maternal Exposure to Medication. Exposure to medication during pregnancy presents a potential hazard. Although only a few drugs have been shown to cause human congenital anatomic defects, others are suspected. Investigators are concerned because of the large number of drugs used by pregnant women. About 1.2 billion drug prescriptions are written for these women each year. In addition, over-the-counter drugs are taken by many pregnant women.

The drug diethylstilbestrol, often referred to as "DES," is a synthetic female sex hormone that, when taken during the first 4 to 6 weeks of pregnancy, has caused genital malforma-

tions in babies of both sexes and, more rarely, vaginal cancer in daughters. These abnormalities are often not evident in the offspring until after puberty.

Techniques for identifying potentially hazardous substances are being developed by NICHD-supported investigators. One method involves the laboratory testing of suspected substances in several species of animals or in tissue culture. Another method involves epidemiological investigations. Most of the known hazardous substances affect only a small number of exposed fetuses, and identifying them requires control studies involving large numbers of pregnant women or case control studies.

Antenatal Diagnosis and Treatment. While current research is yielding information about the causes of congenital defects and other problems in fetal development, efforts to obtain information about the status of the fetus in utero must also be continued. The NICHD encourages research on the development of accurate diagnoses that can provide the basis for treatment, cure, and eventual prevention of fetal abnormalities.

Prenatal detection of hereditary diseases or congenital defects has evolved as a new option in the counseling of many families at increased risk for such conditions in their offspring. For example, antenatal diagnosis is indicated when known risk exists for specific and detectable hereditary diseases or congenital defects. Discovery of a fetal abnormality may permit appropriate treatment in utero or enable the family to plan for special needs of the child.

Amniocentesis, a procedure in which fluid and cells are removed from the amniotic sac by aspiration through the uterine wall, is one of the most widely used techniques for antenatal diagnosis. Both the diagnostic accuracy and the safety of amniocentesis have been confirmed. Nearly 100 genetic metabolic diseases can be diagnosed by means of this process. The amniotic cells are cultured and their chromosomes, or specific enzyme activity, are analyzed. It is possible to diagnose chromosomal anomalies, such as Down syndrome, and metabolic disorders, such as Tay-Sachs disease, by the 20th week of pregnancy.

Other developments in antenatal diagnosis include fetoscopy and ultrasound. In the first process, the fetus can be observed directly through a fiberoptic instrument, and fetal blood samples can also be obtained. In the second, an image of the fetus and placenta can be viewed. Ultrasound also allows the fetal heart rate to be recorded precisely. Recent research has permitted the diagnosis of enzyme deficiencies not expressed in amniotic fluid cells by direct analysis of DNA. Further, as efforts continue to map the

entire human gene complement, more markers linked with genetic disorders will be found. This information should increase the number of known prenatally diagnosable genetic disorders.

Birth Process

The management of pregnancy, labor, and birth may make the difference between a normal, healthy lifespan and early death or many years of handicap. Research supported by the NICHD in maternal and perinatal medicine has resulted in improved health of pregnant women and their infants. Among the research advances is the ability to assess fetal maturity and well-being through evaluation of fetal movement and organ function to determine whether a fetus is ready for extrauterine existence. The techniques of amniocentesis, fetoscopy, and ultrasound are also used to assess fetal growth, position, motion, and lung maturity. These tests are not entirely reliable for indicating fetal distress, however, and research is needed to improve existing techniques and to develop new methods that are accurate and non-invasive.

Other research findings suggest that the fetus itself may help to stimulate the onset of labor by producing a biochemical signal that initiates the synthesis of prostaglandins in fetal and surrounding uterine membranes. The prostaglandins in turn may stimulate or trigger the initiation of the uterine contractions of the birth process.

For most women in labor, electronic monitoring of the fetal heart rate is used to assess fetal status. Specific patterns of change in the fetal heart rate associated with uterine contractions have been identified and correlated with the events of labor. At the NICHD Consensus Conference on Antenatal Diagnosis in March 1979, a panel of experts evaluated the use of continuous monitoring of the fetal heart rate during labor and agreed that this procedure was beneficial for patients at high risk for fetal distress, but should be optional for those at low risk for such complications. These experts also emphasized the need for improved monitoring techniques more predictive of fetal distress.

Investigators and clinicians have also been concerned with determining the safest methods of delivery. When normal spontaneous vaginal delivery may be hazardous for the mother or the fetus, cesarean delivery is employed. This procedure is of particular concern, however, because its use has tripled in the last decade. It was concluded at the NICHD Consensus Development Conference on Cesarean Childbirth in September 1980 that, under certain conditions, women with a previous cesarean delivery can undergo labor and vaginal

delivery with very little risk to the mother or fetus. In addition, the conferees identified four types of obstetrical problems responsible for 80 percent of cesarean deliveries. They recommended additional research to answer fundamental questions about the birth process and to determine the most efficacious clinical procedures for use in the practice of obstetrics.

What remains uncertain are the actual biochemical signals that trigger the birth process. An increased understanding of normal, as well as abnormal labor, may provide clues not only to the origins of premature labor but also to its prevention. NICHD investigators are continuing their research on this most important problem.

The Newborn

In the United States from 1970 to 1978, the most recent years for which final figures are available, infant mortality decreased by 31 percent to 13.8 deaths per 1,000 live births. The estimated rate for 1980 is 12.5 deaths per 1,000 live births. Most of the decline has been in the neonatal period, the first 28 days of life.

There have been significant reductions in the death rates for four of the leading causes of infant mortality: hyaline membrane disease (HMD), respiratory distress syndrome (RDS), asphyxia, and immaturity. These four causes are confined almost entirely to premature infants, which means those who weighed no more than 2,500 grams (about 5.4 pounds), those who were delivered at less than 37 weeks of gestational age, or both. The infants weighing under 1,500 grams (about 3.3 pounds) constitute only 1 percent of all live births but account for two-thirds of neonatal deaths. Furthermore, the remaining leading causes of death in early childhood, with the possible exception of accidents, are more common in premature infants. Nationwide, about 60 percent of all infants who die in the first year were born premature. Among those infants under 1,500 grams who survive, the rate of handicap, ranging from significant learning disabilities to cerebral palsy, has been reported to approach 60 percent by the 8th year. If the overall mortality rate is to be improved, research on the causes and prevention of prematurity is crucial.

Respiratory distress syndrome is a common cause of illness in the premature infant. This disease is characterized by lung immaturity and is caused by an insufficiency of a substance that lines the airspaces and prevents lung collapse during breathing. It has been discovered that drugs such as hydrocortisone, when administered to a mother in premature

labor, can induce fetal lung maturation and prevent the occurrence of the disease in the neonate. Also, use of a technique called continuous positive airway pressure in affected newborns has aided in reducing fatalities. Other techniques currently under investigation include the use of artificial lung substances to line airspaces, and high-frequency ventilation to provide adequate oxygen.

A perinatal disorder that was once a significant problem is erythroblastosis, which results in the destruction of blood cells. In this disorder, an anti-Rh antibody develops in the Rh-negative mother when the fetus is Rh-positive. The antibody crosses the placenta and destroys fetal red blood cells. Until about 1965, erythroblastosis was a significant cause of infant illness and death, but the immunization of Rh-negative women with Rh immune globulin (RhoGam) after delivery of an Rh-positive infant has prevented the sensitization that can lead to the development of erythroblastosis in subsequent pregnancies.

Sophisticated and increasingly successful techniques of life support have made it possible to save premature infants who only a few years ago would have died soon after birth. The survival of large numbers of these low birthweight infants poses nutritional challenges. Protein and energy requirements for maintenance of acceptable rates of extrauterine growth and development must be ascertained, as well as requirements for vitamins, minerals, and trace elements. Efforts must also be made to understand how nutrients can be delivered effectively by advanced methods of parenteral and enteral nutrition.

Human milk is a uniquely appropriate mixture of nutrients for the infant. Data indicate that it serves to protect the infant from newborn infections as well as to provide substances that may facilitate development. Studies of the use of human milk and of the special components of human milk hold promise for offering high-risk infants an opportunity for normal development.

Sudden Infant Death Syndrome. Sudden infant death syndrome (SIDS), or "crib death," occurs most frequently among infants between 1 and 6 months of age. This syndrome is responsible for 6,000 to 7,500 deaths each year, or about 1.5 to 2 per 1,000 live births. SIDS is the leading cause of death in infancy after the first month of life.

NICHD investigators are continuing their research on the origins of SIDS. Multiple causes may be involved. The Institute is supporting an extensive, cooperative epidemiologic study of potential risk factors for SIDS. Data on more than 800 victims of SIDS and 1,600 "matched controls" (surviving infants of otherwise similar characteristics) are being col-

lected by six regional study centers, with the inclusion of both rural and urban populations of different income levels and ethnic compositions. Data from this study may provide information that can help identify infants at risk for SIDS.

Infancy and Childhood

The growth rate of the infant is much faster than that of a child 7 to 10 years old: the infant uses about 25 percent of his energy intake for growth while the older child uses only 2 to 3 percent. Among investigations of ways to increase the understanding of the controls of growth rates and to improve the treatment of growth disorders, research on growth-hormone-deficient dwarfism has received particular attention. Of a population of 100,000 short children, about 1,000 will be found to have true growth-hormone deficiency. The largest subgroup of about 50,000 children will have normal variant short stature. Evidence suggests that about 15 percent of these children can grow taller after treatment with human growth hormone, which is derived from the pituitary glands of cadavers. The scarcity of this hormone led to searches for other sources, and the use of DNA recombinant techniques has made it possible to increase the supply.

Obesity is another form of growth disorder. The prevalence of obesity among American children is associated with gender, race, income, feeding practices, and particularly, obesity in parents. About 37 percent of infants who exceed the 95th percentile of weight for age during the first 6 months of life will become overweight or obese adults. The odds against an overweight child becoming an average-weight adult are estimated to be 4-to-1 at age 12. These odds rise to 28-to-1 among those who fail to reduce during adolescence. The percentage of White obese children, ages 5 to 18 years, is substantially higher among lower income groups than among upper income groups. Urban children also tend to be more obese than rural children. Regardless of whether parents are biological or adoptive, the risk of childhood obesity ranges from 10 to 40 to 80 percent in proportion to whether neither parent is obese, one parent is obese, or both parents are obese.

Current Institute-supported research on physical growth includes studies of the basic biophysical and radiological aspects of skeletal development and mineral density of bone. Over the years, the study of body composition has advanced from measurements of body weight and skinfold thickness to determination of fat-cell size and number, analysis of the lipid content of fat cells, and measurement of changes in volume. Studies that include measurements of physical growth

and identification of factors influencing rates of growth provide important indicators of long-term health status and potential problems.

Nutrition, Growth, and Development. The relation between nutrition and physical growth and development is an area of increasing interest to the NICHD. It has been found, for example, that because the growth rate in the human species is slower and lasts longer than that in most other species, nutritional needs appear to be less in humans. Also, nutritional needs vary during the life cycle and depend upon physiological changes, as illustrated by the growth rate and energy consumption of the infant. Insufficient intake of energy and nutrients during early life may cause retardation of physical growth and have a permanent influence on adult stature.

It has been found that the utilization and storage of nutrients vary with the stages of growth and development. The example of altered utilization of iron during pregnancy was cited earlier. Another example is the altered absorption of iron from breast milk. Although reported values for iron in breast milk are low, iron-deficiency anemia is rare in breast-fed infants. In fact, the blood of infants who are breast fed for the first 6 months of life has a concentration of iron equal to that of infants fed fortified formulas. This finding suggests that infant utilization of iron from human milk is more efficient than that from cow milk. The reason for this difference is not yet known.

Food selection and absorption are affected by genetic differences. For example, primary lactose intolerance--an inability to digest milk sugar--appears to be genetically predetermined. This condition is common among children of particular ethnic groups. Almost 90 percent of Black, Mexican American, and American Indian populations have an intolerance for lactose, but only about 30 percent of White children cannot tolerate lactose.

Data from NICHD investigations of environmental and nutritional interactions suggest that overall growth and development of children are affected by variations in their social environment and early emotional experience. Early disturbances of the interaction between mother and infant, including feeding disturbances, can retard weight gain and significantly affect physical and behavioral development. Preliminary research findings suggest that affected children who are given nutritional supplementation are socially more responsive, more interested in school work, and more active during early school years.

Nutritional imbalances and interactions in early life may underlie subsequent medical problems in adults. In ad-

dition, dietary practices, which may be established by early exposure to foods, tastes, smells, and patterns of food consumption, may be as important as the adequacy of nutrient intake in influencing health. In general, many NICHD investigators believe that nutritional status is influenced by genetic makeup but that environmental factors probably have the greatest overall, long-term influence on food choices and intake, and therefore, on nutritional status.

Behavioral Development. Infants respond to and interact with their environment at birth, and they are able to learn and communicate long before the emergence of language. The first 2 years after birth are a time of rapid behavioral change and development. Infants make ever increasing contact with their environment, and the resulting interaction lays the groundwork for later behavior.

The infant's recognition of visual and auditory stimuli and patterns has been measured by motor responses such as eye and head movements and sucking, as well as by physiological responses such as changes in heart rate. With these methods, NICHD investigators have tracked the growth of cognition and learning ability. Such studies make it possible to assess the condition of infants who are born at risk for abnormal development and to evaluate the effects on these infants of the environment and of programs of stimulation.

The infant's visual and auditory systems mature rapidly during the first few months. Certain types of sights and sounds are perceived and responded to even at birth. The ability to see color and pattern, for example, appears to be present at birth, and very young infants are able to discriminate between a significant number of speech sounds.

Childhood is a period of transition from a sensory-motor-based system of awareness to one that is symbolically based. The NICHD has encouraged research on the kinds of responses young children are capable of making and on ways that allow children to show what they are able to do. Areas of ability have been identified, including number development and memory development, but many basic questions remain unanswered. What components can be identified in perception of complex situations or events? Which of the components are most central to development? How are they acquired?

Social and emotional development in infancy is characterized by changing behavioral patterns. The caregiver is used by the year-old infant as a base for exploration. In the presence of the caregiver, novel objects or strangers can be tolerated, and contact with the caregiver helps to terminate distress and so promote exploration. This type of behavior changes in toddlers. Seeking and maintaining physical contact with the caregiver diminishes, but toddlers maintain

psychological contact by seeing and hearing the caregiver and through the sharing of play. Even when toddlers do not seek visual contact with the caregiver, they are reassured by the opportunity to do so. Increasingly, toddlers utilize their own resources first, then rely on the caregiver when necessary. At the same time, the function of the caregiver expands from the provision of affection and comfort to include guidance and limit setting.

Results of recent research supported by the Institute on the social development of young children have also shown that the capacity of very young children to engage in constructive interaction with age-mates is greater than was previously believed. In studies of extrafamilial influences, it has been found that good quality out-of-home day care does not have negative effects and, in part, may be beneficial.

Social and emotional development in middle childhood has not been a major subject of research, probably because of the supposition that middle childhood is a latent period. Moreover, it is difficult to study the school-age child outside the classroom. The bulk of recent progress has occurred with school-related issues, such as relating achievement to the development of the ability to understand and reason. Progress has also been made in understanding the child's social development and the development of a sense of morality. Little is known, however, about the manner in which children's changing understanding of the social universe affects their behavior with peers, teachers, and family members, and how these changes influence the concept of self.

Speech and Language Development. An estimated 10 million people in the United States have a speech or language disorder that significantly interferes with communication, and about 25 percent of students have reading problems. These estimates illustrate the need to study communication ability and the acquisition of speech and language.

New techniques have been developed by NICHD investigators for studying perception and memory of speech sounds in infants, as well as the role of auditory feedback in speech development. Measurement of changes in heart rate and electrical brain waves has shown, for example, that newborns can clearly distinguish between pure tones and complex speech-like sounds. Speech development correlates with heart rate and EEG.

Results of studies show that children are more sensitive to their listeners' needs than had previously been thought. They talk more simply to younger children than to peers or adults, describe subjects more clearly to a blindfolded listener than to a listener who can see, and show many other signs of being able to take a listener's informational needs into account.

Some children have the reading disability called dyslexia, where reading ability is below expectations for their age but where their development otherwise appears to be nornormal. The etiology of this condition is unknown, but reading experts agree on several points: dyslexia has different forms, there are probably multiple causes, and the source of the problem may lie within the psychophysiologic makeup of the child rather than in environmental influences. One factor that is strongly implicated is an inability to make a linkage between spoken language and written language. Genetic involvement is suggested by the observations that the condition seems to run in families and that boys are 3 to 6 times more likely to be afflicted than girls.

Tests developed with NICHD support are useful not only for diagnosing a reading disability but also for prescribing remedial procedures for children with reading problems. Nevertheless, dyslexia remains a puzzling and complex disorder that requires continuing research.

Mental Retardation. Mental retardation is a chronic disability identified clinically by several signs that include a significant impairment of intelligence and a deficit in adaptive behavior. Depending upon the definition used, estimates of the number of mentally retarded range from 2.2 to 6.6 million. The number is still higher if less severely affected individuals are included, such as those whose IQ is less than 80 and whose social adaptation poses problems.

Causes of mental retardation are biological, psychological, and social, and they may occur singly or in combination. Genetic defects, metabolic disorders, and prematurity or other prenatal disturbances are among some 200 identified or suspected causes Infection or injury at birth or in early childhood can also cause mental retardation. Additional causes may include lack of stimulation, nutritional inadequacies, inadequate educational opportunities, and generally deficient living conditions. Investigators have devoted attention to aberrant developmental processes that contribute to mental retardation and to social forces that affect the retarded.

Progress has been made during the past decade in large part as a result of NICHD research in understanding specific disturbances that may cause mental retardation. For example, increased understanding of inherited diseases of metabolism and disturbances caused by exposure to toxic substances--either in utero or postnatally--has resulted in advances in treatment and prevention. Specific hazardous situations include ingestion of alcohol during pregnancy and ingestion of lead by children.

Behavioral and psychological deficits associated with mental retardation can lead to critical problems of adapta-

tion, and the NICHD is supporting major efforts to identify specific deficits and alleviate the problems that they cause. The mentally retarded, for example, have difficulty in transferring information from short-term memory to long-term memory and an inability to link new information to previously learned material. These processes are being studied in mentally retarded young children and infants so that they can be taught how to generalize from one learned task to others. In addition, children with limited intelligence can be taught to solve problems when the information is presented in ways that are appropriate to their capacity.

The kinds and extent of deficits in language abilities vary among the retarded, and investigators have questioned whether language acquisition is simply delayed or whether there are qualitative differences as well. Attempts to resolve these questions include the determination of how those who are verbally retarded can be helped to communicate by use of other cues as signs and how the language processing ability of preschool children is related to subsequent "reading readiness." A current trend is to study the use of language in natural settings in which small children socialize, communicate with others, process information, and perceive the world.

Defining the interaction of biological and behavioral factors that cause mental retardation is the goal of many studies supported by the Institute. Such knowledge forms the basis for designing methods to help individuals adapt to new situations, particularly community settings, and to improve the treatment and prevention of retardation.

Adolescence

The NICHD is supporting research to provide new data on adolescent development from various perspectives that include cognitive, emotional, and social development during adolescence; patterns of interaction with family, peers, and school; and behavioral endocrinology of puberty.

Researchers supported by the NICHD have advanced the understanding of control mechanisms that lie behind the sexual, somatic, and psychological transformations collectively known as puberty. It has been shown in a variety of animal models, for instance, that the onset of puberty begins with neurochemical signals that emanate from cells in the midbrain. These signals trigger the release of luteinizing hormone releasing hormone (LHRH). LHRH, in turn, stimulates the pituitary to release luteinizing hormone (LH) into the blood. Surges in LH concentration during sleep in prepubertal children are the first detectable signal of the onset of puberty, one that appears months before the earli-

est clinically apparent physical changes. The appearance of this characteristic pattern of LH is already proving useful in following children in whom pubertal onset has been delayed, and treatment of the disorder is possible in some instances, as is treatment of precocious puberty, a condition in which sexual maturation begins several years earlier than normal.

Adolescence is a period in which the ability to reason abstractly is expanded and an awareness of one's participation and position in society is acquired. Research on adolescence has been limited. Studies to date, conducted almost exclusively in classroom situations, have emphasized achievement, social relations, autonomy, identity, and sexuality. Studies in progress, however, include research on the development of complex problem-solving abilities, reasoning, and scientific thinking, and on the differential effect of adolescent experience on males and females.

In efforts to understand adolescence, it is important to realize that the period from early puberty to late adolescence spans 11 years--from about age 10 to 21--and encompasses a number of maturational stages. Unanswered questions about early adolescence relate to the transition from preadolescence to adolescence, which is a period of rapid physical and psychosocial development. Generally stressful and characterized by a "present" orientation, this period is often associated with rebelliousness and risk-taking behavior. Evidence points to early adolescence as a period of transformation in social relations involving the family and friends rather than, as was previously believed, a period in which these early relationships are dissolved. Older adolescents, in contrast, are "future" oriented, have more ties with their peer groups, and are concerned with their developing adulthood and their self-image, social competence, and career choices.

Adolescent Pregnancy. In the 1970s, the numbers of births to teenage women was high, out-of-wedlock births increased, and the number of births to very young adolescents increased. Given the association of early childbearing with low birthweight babies and other adverse pregnancy outcomes that is strongest for mothers younger than 15, a broad program of research was begun. Research findings indicate that the risks, especially among the very young, are a mixture of social and biological factors including maternal size and nutrition, such as maternal height, weight, and weight gain during pregnancy. A few recently advanced data suggest that high quality prenatal care offsets these risks; however, an adequately controlled clinical trial of the effects of prenatal care remains to be done. The long-term picture is more complicated, and it is influenced by family structure. Children raised by teenage mothers alone do not fare as well as

those raised with another adult present. They statistically have lower academic aptitudes than other children. This effect can be partly explained by their having to live in single-parent, step-parent, or no-parent families. These children are also at risk of repeating their parent's early marriage, early parenthood, and higher fertility.

Research also deals with the social and economic factors associated with adolescent childbearing. Teenage mothers bear more children over their lifetimes than do women who begin childbearing later in life, they have more unwanted births and more out-of-wedlock births, and they have completed less education, even when background factors are taken into account. The combination of larger family size and less education leads to lower economic status later in life and a greater likelihood of need for welfare assistance. Since marriages are less stable for young brides, there is less likelihood that a teenage mother will continue to have the help of a husband in raising her children.

The effects of early childbearing are remarkably persistent. For example, women in second marriages who first married as teenagers have higher rates of marital dissolution in later marriages. Although many young women go back to school after dropping out to have a baby, they do not catch up with their peers who become mothers at a later age. The NICHD supports research to better understand the implications of adolescent childbearing and childrearing and to determine the physiological and psychological consequences of very early pregnancy for mothers, children, and other family members.

Families and Populations

Research in human development is concerned also with changes in families and larger populations. Current patterns of fertility behavior, for instance, show several departures from the recent past. There has been an increase both in childlessness and in one-child families. Many women from the post-World War II "baby boom" era have delayed having a first birth, and as a result first-birth rates are rising for women in their late twenties and early thirties. While most childless women say that they intend to bear children, the implied high rates of reproduction at the later childbearing ages seem unlikely to occur. This observation means either a surge of childbearing, a downward revision in expected family size, or a tendency in both directions.

Data have suggested that women's wages are the single most important factor in recent fertility trends, but there are complex interactions between childbearing and women's employment. Higher wages are associated with lower rates of

reproduction, longer postponement of childbearing, and increased participation in the labor force, but in contrast, the economic demands of several children are associated with increased female employment. Knowledge about methods of contraception usually influences a couple's decisions on how to control their fertility, but social and economic factors often determine the extent to which it is controlled. A young adult's commitment to the labor force and the level of his or her earnings affect the timing of marriage and reproduction.

The recent trend toward declining mortality among the middle-aged and elderly has raised important questions about social and living arrangements in relation to health. Data show, for example, that married people at any given age tend to be healthier than unmarried people of the same age and that older people who live with others retain their health longer than those who live alone.

The structure of the U. S. population is changing also because of rapid changes in living arrangements. The movement of people within the United States, for instance, causes local areas to change in population size and characteristics, and while such movement is often economically beneficial, it may disrupt families, households, and other support networks. In addition, larger proportions of children are spending at least part of their lives, because of the increase in divorces, in single-parent households. Such experiences may have long-lasting effects and should be studied.

Changes in age composition of the population may have substantial implications for national health and health policies. The recent decline in the rate of reproduction contributes to a decrease in the proportion of the population at young ages. More importantly, the large number of young adults who were born during the baby boom will begin to reach age 65 in 2010. At that time, the proportion of the population that is older will begin to increase rapidly.

Future Directions

The acquisition of fundamental knowledge about human development remains one of the most profound challenges of modern biomedical and behavioral science. The research programs conducted and sponsored by the NICHD are directed toward increasing understanding of the various aspects of development--the transformation of a fertilized egg into an infant, the growth of an infant into a healthy productive adolescent and adult, the development of human reproductive systems, and the changes affecting the health and behavior of individuals, families, and populations.

Research advances have helped solve some of the special problems of men, women, and children as members of families and of populations. The emphasis on learning about early development, when many diseases and disorders originate, has resulted in opportunities to contribute to the prevention of many major physical and mental problems of adult life. These research advances have also expanded the fundamental science base, revealed gaps in knowledge, and suggested new directions for potentially significant further research. On the basis of this accumulated information, the NICHD has established priorities for research directed toward the acquisition of new knowledge for continuing progress in preventive medicine.

Research Plans

Introduction

In developing the research plans, the Steering Committee used the evaluation reports generated by the Study Groups as bases for identification of future research needs and opportunities. The strategy for planning, which involved an examination of existing NICHD research activity with reference to the recommendations of the 10 Study Groups, was in three stages. In the first stage, Task Forces of the Steering Committee reviewed the recommendations of the Study Groups and ranked them in order of their relevance and importance to the Institute's mission. In the second stage, members of the extramural staff of the Institute used the Task Force conclusions and data on existing program activity to develop overall program goals and research implementation plans. In the third stage, the Steering Committee considered and acted on each plan individually.

The program goals for each area, along with actions proposed for Fiscal Year 1983, appear on the following pages. The availability of resources, new research opportunities, and findings from ongoing research may require that the Institute modify some research actions or postpone their implementation.

Guide to Abbreviations Used in the Research Plans

ADAMHA--Alcohol, Drug Abuse, and Mental Health Administration

CDC--Centers for Disease Control

DNA--deoxyribonucleic acid

EPA--Environmental Protection Agency

FDA--Food and Drug Administration

FY--fiscal year

HSA--Health Services Administration

IUD--intrauterine device

IUGR--intrauterine growth retardation

LHRH--luteinizing hormone releasing hormone

MRRC--Mental Retardation Research Center

NCHCT--National Center for Health Care Technology

NCI--National Cancer Institute

NEI--National Eye Institute

NHLBI--National Heart, Lung, and Blood Institute

NIA--National Institute on Aging

NIADDK--National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases

NIAID--National Institute of Allergy and Infectious Diseases

NICHD--National Institute of Child Health and Human Development

NIEHS--National Institute of Environmental Health Sciences

NIGMS--National Institute of General Medical Sciences

NIH--National Institutes of Health

NIMH--National Institute of Mental Health

NINCDS--National Institute of Neurological and Communicative Disorders and Stroke

NIOSH--National Institute of Occupational Safety and Health

PKU--phenylketonuria

RFP--request for proposals (contracts)

SIDS--Sudden Infant Death Syndrome

UAF--University Affiliated Facility

Fertility and Infertility

Research on fertility and infertility can advance the knowledge that is needed to maintain the health of human reproductive systems, cure diseases associated with reproduction, and alleviate infertility. In addition, it can lead to safer and more effective means of regulating fertility. It is focused on the study of the reproductive processes of men and women and of animals with similar reproductive systems.

The area subsumes four fields of reproductive science: endocrinology, biology, medicine, and chemistry. The first involves the study of the endocrine glands and of the metabolism of the reproductive hormones they secrete; the second, of the processes of ovulation, spermatogenesis, fertilization, and early embryonic development. Reproductive medicine is concerned with nutritional aspects of fertility and with reproductive diseases and disorders, and it includes clinical studies of human reproduction. In reproductive chemistry, research is focused on isolating and synthesizing the substances involved in reproduction.

The program goals for research on Fertility and Infertility are:

Fundamental Science Base: To support investigator-initiated research in the reproductive sciences of highest scientific merit in order to establish and maintain the minimum fundamental science base required for the achievement of remaining program goals. (Recommendations 1 through 6)

Human Infertility: To develop new knowledge that can be applied to alleviate and(or) cure human infertility. (Recommendations 7 through 11)

Reproductive Diseases and Disorders: To alleviate or cure human reproductive diseases or disorders. (Recommendations 12 through 16)

Fertility Regulation: To identify and develop new leads for basic research for less hazardous and more effective methods of fertility regulation. (Recommendations 17 through 21)

Research Plan

Fundamental Science Base. Program Goal: To support investigator-initiated research in the reproductive sciences of highest scientific merit in order to establish and maintain the minimum fundamental science base required for the achievement of the remaining program goals. (Fiscal Year 1981, est., $43,420,000)

OBJECTIVE	ACTION	NOTES
1. Study gamete transport in mammalian reproductive tracts.	Increase basic knowledge of gamete transport for better understanding of fertility and infertility.	
2. Conduct basic studies in reproductive genetics.	Enhance fundamental science base for understanding chromosomal disorders.	Coordinate with the NICHD Work Group on Genetics and Teratology.
3. Support animal studies on in vitro fertilization, embryo transfer, and embryonic and endometrial synchrony for implantation.	Develop a program announcement for studies in non-human primates.	Basic knowledge on fertilization and implantation in mammals is needed to help alleviate disorders of infertility.
4. Develop new technologies such as hybridomas and recombinant DNA.	Increase fundamental science base on reproduction. Plan a research workshop on gene regulation to identify broad areas of research.	Coordinate with the NIADDK. The production of single monoclonal antibodies serves as a potent new biotechnology in reproduction.
5. Support basic research on the biosynthesis, secretion, and action of reproductive hormones.	Increase fundamental science base to understand the endocrinology of reproduction.	Cosponsor, in the summer of 1982, the Ovarian Workshop with Society for Study of Reproduction.
6. Conduct further studies on fundamental reproductive neuroendocrinology.	Develop basic knowledge on the control of reproductive processes by the brain and other components of the nervous system.	New knowledge in this area is essential to understanding fertility and infertility.

Human Infertility. Program Goal: To develop new knowledge that can be applied to alleviate and(or) cure human infertility. (Fiscal Year 1981, est., $1,798,000)

OBJECTIVE	ACTION	NOTES
7. Support fundamental research on gonadotropin releasing hormone and its analogs; study new methods for detection of human chorionic gonadotropin.	Develop new understandings on safer, more efficacious means of ovulation induction and prediction. Develop methods for early detection of ectopic pregnancy.	Coordinate internally with research program on Contraceptive Development.
8. Conduct basic studies on human tubal physiology, gamete transport, and cervical mucus.	Provide a scientific basis for correction of fallopian tubal abnormalities and defects and for self-evaluation of cervical mucus.	Consult with American Fertility Society and with natural family planning groups.
9. Study the mechanisms for stimulating sperm production and develop better methods to evaluate sperm quality.	Identify new approaches to treatment of male infertility.	Utilize findings and recommendations of the NICHD Testes Workshop.
10. Study the suppression of testosterone production in women.	Develop methods to alleviate infertility in women due to hypersecretion of testosterone.	Consult with the Society for Gynecological Investigation.
11. Determine mechanisms of follicular growth and ovulation.	Increase fundamental science base on ovarian physiology.	Cosponsor, in the summer of 1982, the Ovarian Workshop with the Society for Study of Reproduction.

Reproductive Diseases and Disorders. Program Goal: To alleviate or cure human reproductive diseases or disorders. (Fiscal Year 1981, est., $1,261,000)

OBJECTIVE	ACTION	NOTES
12. Elucidate the role of endogenous opioids in reproduction.	Develop program announcement.	Coordinate with the NINCDS.
13. Study catecholamines as neurotransmitters in reproduction.	Develop program announcement.	Coordinate with the NINCDS. Further studies of the role of catecholamines in modulating hypothalamic hormone secretions and the role of dopamine in acting as a prolactin inhibiting factor are of urgent importance.

14. Study female reproductive dysfunction including dysmenorrhea, endometriosis, exercise-induced amenorrhea, and immune or autoimmune disease.	Develop program announcement; encourage studies on the etiology and amelioration of reproductive dysfunction in women.	Coordinate with the American College of Obstetricians and Gynecologists.
	Develop new knowledge on the role of nutrition in menstrual dysfunction.	Coordinate internally with research program on Nutrition.
15. Conduct research on reproductive toxicology and the environment.	Convene experts in field to assist in identifying new research questions.	Broad emphasis on reproductive toxicology deserves considerable attention in view of risk for both male and female.
		Coordinate with NIEHS and NIOSH on possible conference or research workshop.
16. Investigate male gonadal dysfunction.	Increase studies on andrology including factors affecting and controlling male reproductive processes and plan a workshop on reproductive disease.	

Fertility Regulation. Program Goal: To identify and develop new leads for basic research for less hazardous and more effective methods of fertility regulation. (Fiscal Year 1981, est., $798,000)

OBJECTIVE	ACTION	NOTES
17. Support fundamental work on gonadotropin releasing hormone analogs and on endogenous putative peptides.	Increase clinical work and studies on subhuman primates.	Coordinate internally with research program on Contraceptive Development and consult with the Society for the Study of Reproduction and with the Endocrine Society.
	Achieve purification of the peptides, establish assay methods, and develop trials in laboratory animals.	
18. Develop new understandings on Sertoli cell-germ cell interaction and sperm maturation.	Clarify the regional difference in epididymal function in sperm maturation; and clarify sperm motility acquisition.	Consult with the American Society of Andrology.
19. Study immunocontraception using antigens of sperm and zona pellucida.	Expand utilization of monoclonal antibody techniques.	Consult with a panel of immunologists.
20. Study the regulation of gonadal membrane receptors for reproductive peptide hormones.	Increase clinical work and studies on subhuman primates.	Consult with the Endocrine Society.
21. Study the regulatory mechanism of oocyte maturation.	Clarify factors involved in the oocyte maturation and their control mechanisms.	

Pregnancy, Birth, and the Infant

The events of pregnancy, labor, and birth are the major determinants of lifetime well-being, and the birth of a healthy infant is a happy occasion in family life. Problems during pregnancy and early development, however, can have tragic consequences. Infants who survive a complicated intrauterine existence, a difficult birth process, or serious neonatal diseases may never achieve their full potential, but early recognition of risks during the fetal or newborn period can allow for interventions to prevent long-term disabilities.

In the last decade, significant advances were made in the management of maternal illnesses during pregnancy and in neonatal intensive care. They have resulted in a marked decrease in mortality. Accompanying these advances, however, the increased number of low birthweight newborns who survive has introduced a new set of problems. As a group, premature and very low birthweight infants continue to have a high mortality rate; survivors often suffer long-term handicaps. Preventing such premature births will make it possible to improve and assure the health of infants.

To achieve this goal, it is necessary to understand the biological, anatomical, and functional interrelationships of the maternal organism, developing fetus, and environment. Research in this area includes basic and clinical studies of fetal pathophysiology under various conditions, and genetic and environmental aspects of normal and abnormal pregnancies. It encompasses such disciplines as pharmacology, microbiology, and toxicology. Clarification of normal processes will help in identifying high-risk situations. Research is also needed for a better understanding of the birth process and factors responsible for the initiation of labor in order to assure the delivery of a mature infant who can thrive independently.

The program goals for research on Pregnancy, Birth, and the Infant are:

Normal and Abnormal Pregnancies: To develop scientific information on normal and high-risk pregnancies to improve the outcome of pregnancy for both mother and infant. (Recommendations 1 through 7)

Fetal Development and Maturation: To develop scientific information on normal and abnormal processes of fetal development and maturation that will lead to a reduction in infant mortality and morbidity. (Recommendations 8 through 10)

Labor and Birth: To develop scientific information on the normal and abnormal events leading to the initiation of labor and the normal and pathologic processes of delivery to reduce the incidence of prematurity and birth injury. (Recommendations 11 through 13)

Newborn Adaptation: To develop scientific information regarding the normal and abnormal adaptation of the newborn infant to extrauterine existence and the disorders specifically affecting the newborn to reduce neonatal mortality and long-term morbidity. (Recommendations 14 through 19)

Research Plan

Normal and Abnormal Pregnancies. Program Goal: To develop scientific information on normal and high-risk pregnancies to improve the outcome of pregnancy for both mother and infant. (Fiscal year 1981, est., $9,364,000).

OBJECTIVE	ACTION	NOTES
1. Determine the mechanism responsible for the development of pregnancy-induced hypertension and improve methods of diagnosis and treatment.	Assess existing program in the first year; develop selected program announcement in second year.	Coordinate with NHLBI and NIADDK.
2. Develop improved methods of managing diabetic pregnancies and study the effect of these methods on pregnancy outcome.	Continue support of existing research portfolio.	Coordinate with NICHD Epidemiology and Biometry Research Program on contract study of diabetes control and congenital malformations.

3. Study the pathogenesis and effects of apparent and inapparent maternal infections on the fetus and develop improved methods of treatment and prevention.	Evaluate recommendations from research planning workshop on Maternal Infections and Pregnancy Outcome held in May, 1981; publish results of workshop and consider a program announcement in first year; assess program in second year.	Coordinate with NIAID and Bureau of Biologics, FDA.
4. Examine immunological interactions between the maternal organism and the developing fetus.	Assess existing program. Identify areas for possible inclusion in a program announcement on maternal infections.	Coordinate internally with research program on Congenital Defects.
5. Assess impact of maternal diet on fetal development and maternal disorders of pregnancy.	Use staff programming to stimulate research activity.	Coordinate internally with research programs on Nutrition, Congenital Defects, and Mental Retardation.
6. Develop more specific methods to diagnose and treat hematologic disorders in mother and fetus.	Examine current holdings and determine future needs for staff programming.	Collaborate with the NHLBI.
7. Assess the biologic and social impact of teenage pregnancy on mother and infant.	Assess existing research portfolio and review medical literature in first year. In second year, hold a research planning workshop on biologic factors in early teenage pregnancy and their effects upon mother and infant; evaluate recommendations from workshop.	Collaborate with Office for Maternal and Child Health, HSA. Collaborate internally with research program on Population Dynamics and with NICHD Epidemiology and Biometry Research Program.

Fetal Development and Maturation. Program Goal: To develop scientific information on normal and abnormal processes of fetal development and maturation that will lead to a reduction in infant mortality and morbidity. (Fiscal Year 1981, est., $5,861,000)

OBJECTIVE	ACTION	NOTES
8. Assess the effects on mother and fetus of exposure during pregnancy to pharmaceuticals, teratogens, and environmental hazards.	Analyze data from existing files and plan a research workshop to develop recommendations for future research emphasis; publish results of workshop.	Coordinate with NIOSH, EPA, and NIEHS; collaborate with the NICHD Epidemiology and Biometry Research Program and with research program on Congenital Defects.

9. Improve the methodology for diagnosis and expand the applications for diagnosing fetal status (amniocentesis, ultrasound), growth, position, maturity, and well being.	Use staff programming; consider a research planning workshop in second year to update recommendations from the NICHD Antenatal Diagnosis Consensus Development Conference held in March, 1979.	Collaborate with the NHLBI and NIADDK and coordinate internally with research program on Mental Retardation.
10. Search for and develop improved methods for diagnosing developmental defects in utero.	Use staff programming; consider a research planning workshop in second year to update recommendations from the NICHD Antenatal Diagnosis Consensus Development Conference held in March, 1979.	Collaborate with CDC, NINCDS, NCHCT, and FDA, and coordinate internally with research program on Congenital Defects.

Labor and Birth. Program Goal: To develop scientific information on the normal and abnormal events leading to the initiation of labor and the normal and pathologic processes of delivery to reduce the incidence of prematurity and birth injury. (Fiscal Year 1981, est., $3,315,000).

OBJECTIVE	ACTION	NOTES
11. Evaluate hormonal and anatomical factors and mechanisms responsible for maintaining pregnancy, initiating labor, and facilitating its progress. Develop and evaluate methods for safely arresting premature labor.	Assess existing program. Evaluate recommendations from May, 1981 research planning workshop on Maternal Infections and Outcome of Pregnancy (as it relates to labor). On these bases, consider a possible program announcement in the second year.	
12. Encourage the development of improved methods to assess fetal well-being and fetal distress prior to and during labor.	Assess existing program.	Collaborate with the NHLBI and NINCDS.
13. Evaluate the outcome of pregnancies with various complications of labor.	Develop program announcement in first year and identify research needs dependent upon reponse to program announcement.	

Newborn Adaptation. Program Goal: To develop scientific information regarding the normal and abnormal adaptation of the newborn infant to extrauterine existence and the disorders specifically affecting the newborn to reduce neonatal mortality and long-term morbidity. (Fiscal Year 1981, est., $4,730,000)

OBJECTIVE	ACTION	NOTES
14. Develop and assess improved methods of prevention and treatment of respiratory distress syndrome and its complications.	Continue, summarize, and evaluate existing research program.	Collaborate with the NHLBI.
15. Develop improved methods for early diagnosis, prevention, and treatment of neonatal infections.	Evaluate recommendations from research planning workshop on Maternal Infections and Pregnancy Outcome held in May, 1981; publish results of workshop and consider a program announcement.	Collaborate with the NIAID, and Bureau of Biologics, FDA.
16. Improve methods of prevention of Rh hemolytic disease and its sequelae.	Plan a research workshop to discuss Rho-Gam administration during pregnancy.	Collaborate with NHLBI, CDC, and HSA.
17. Assess long-term outcome of very low birthweight infants.	Review and evaluate existing data. Receive guidance recommendations from experts in field for the development of a research announcement in second year of plan.	Collaborate with NINCDS and coordinate internally with research program on Mental Retardation.
18. Stimulate studies to clarify the pathophysiology, develop better diagnostic methods and treatment of neonatal disorders, such as persistent fetal circulation, necrotizing enterocolitis, and metabolic problems.	Assess existing program and identify areas for increased efforts. On this basis, develop a program announcement in specific areas in second year of plan.	Collaborate with NHLBI, CDC, and NIADDK. Collaborate with Office for Maternal and Child Health, HSA. Coordinate internally with research programs on Nutrition, Congenital Defects, and Mental Retardation.
19. Study differences in the disposition and effects of pharmacologic agents on the newborn infant at various ages and weights.	Assess existing program and identify specific needs in conjunction with planned review on fetal exposure to maternal medications.	Collaborate with NIGMS and FDA, and coordinate internally with research program on Congenital Defects.

Nutrition

Nutrition research focuses on the continuum of human development and emphasizes preventive approaches to nutrition-related conditions and stresses health promotion as well as disease prevention. The research is interdisciplinary and involves genetic, biochemical, developmental, anthropometric, behavioral, and cultural aspects.

Research on infant and child nutrition is focused on the nutrient requirements of normal, premature, and growth-retarded infants, including the analysis of human milk, cow milk, and synthetic formules, and on nutritional factors of cerebral and somatic development. In addition, research is undertaken on the nutritional relationship of the mother and her fetus, on abnormal metabolism of nutrient substrates, including the biochemistry and genetics of inborn errors that are, or may prove to be amenable to therapy, and on the functional development of the gastrointestinal tract and on the mechanisms by which foods stimulate the gastrointestinal system.

New horizons of the field include cultural and behavioral determinants of nutritional individuality, nutritional antecedents of adult disease, the involvement of vitamins and trace elements in reproductive processes, nutritional aspects of the adolescent growth spurt and problems of adolescent obesity, and methods for assessing nutritional status, particularly during infancy, adolescence, pregnancy, and lactation.

The program goals for research on Nutrition are:

Maternal-Fetal Nutrition: To better understand the complex relationship between the mother and her fetus and the means by which nutrients pass from one to the other. (Recommendations 1 through 5)

Infant Nutrition: To determine the nutrient requirements of normal, premature, and growth-retarded infants and to analyze the influence of human milk and synthetic formula on optimal infant development. (Recommendations 6 and 7)

Dietary Therapy of Inborn Errors of Metabolism: To assess the effect of diet on inborn errors of metabolism, especially those diseases that are amenable to nutritional management. (Recommendation 8)

Nutrition and Reproduction: To understand the involvement of nutritional factors such as vitamins and minerals in reproductive processes, the reproductive consequences of low protein diet, and the relationship of food resources to reproduction. (Recommendation 9)

Nutritional Antecedents of Adult Disease: To identify factors responsible for and prevent the development of obesity, insulin resistance, and adipose tissue in both normal and obese children. (Recommendation 10)

Nutritional Aspects of Gastrointestinal Development: To understand the process of cellular differentiation and its relationship to functional development of the intestine and to understand and develop methods for nutritional management of digestive and absorptive disorders in human infants, children, and adolescents. (Recommendations 11 through 13)

Nutrition and Development: To better understand: (a) the role of nutrition as a potentiating factor in brain development; (b) the effect of nutritional deficit and excesses in physical growth and maturation; and (c) the effects of non-nutritional food components on growth, development, and health of children. (Recommendations 14 and 15)

Cultural and Behavioral Aspects of Nutrition: To understand the influence of nutritional individuality and cultural and behavioral factors on diet, taste development, food avoidances, and food preferences. (Recommendation 16)

Assessment of Nutritional Status: To develop new methods to assess nutritional status focusing on methodologies that are noninvasive and pose the least possible risk to the individual while being both precise and convenient. (Recommendation 17)

Adolescence and Nutrition: To identify the nutritional needs that occur during this period of profound transformation. (Recommendations 18 through 20)

Research Plan

Maternal-Fetal Nutrition. Program Goal: To better understand the complex relationship between the mother and her fetus and the means by which nutrients pass from one to the other. (Fiscal Year 1981, est., $2,980,000)

OBJECTIVE	ACTION	NOTES
1. Determine the effects of iron, zinc, chromium, and copper during pregnancy on maternal nutrition and function and on fetal growth and development.	Plan a workshop or scientific seminar; identify areas for study on new methodologies for assessment; develop program announcement for FY 1982 and FY 1983.	U.S.-Japan Malnutrition Panel has already issued a multi-institute program announcement. Collaborative research might be done with the FDA and NIADDK.
2. Determine nutritional requirements of pregnant women with metabolic disorders (obesity, diabetes mellitus, hypertension, or inborn errors of metabolism).	Strengthen NICHD Major Research Programs in selected areas such as diabetes; encourage Mental Retardation Research Centers to develop research on inborn errors of metabolism and pregnancy.	Coordinate internally with research program on Mental Retardation.
3. Understand mechanisms fundamental to identifying the fetus predisposed to intrauterine growth retardation (IUGR); develop curative procedures for treatment in utero.	Analyze data from NINCDS Collaborative Perinatal Study to identify concomitants of IUGR; develop suitable animal model; develop a program announcement for grants; plan a conference on nutrition and IUGR in FY 1982.	Coordinate internally with research activities on Pregnancy, Birth, and the Infant. Allow 5 years for program development and support.
4. Determine the effect of maternal weight gains on fetal or neonatal status.	Analyze existing longitudinal data files.	Collaborate with the CDC.
5. Identify nutritional factors that affect perinatal mortality and morbidity.	Use existing longitudinal data files.	

Infant Nutrition. Program Goal: To determine the nutrient requirements of normal, premature, and growth-retarded infants and to analyze the influence of human milk and synthetic formula on optimal infant development. (Fiscal Year 1981, est., $5,017,000)

OBJECTIVE	ACTION	NOTES
6. Determine the effects of parenteral and enteral nutrition on gastrointestinal development and function and on long-term behavioral and functional outcomes.	Develop program announcement for grant applications with designated funding. Build upon research portfolio generated by 1977 Request for Applications on "Infant Nutrition" (25 grants and 2 program projects).	The NIADDK has a major interest in parenteral nutrition for adults.

7. Study effects of human milk and commercial formulas on the growth and health of low birthweight infants.	Assess existing program on this topic; consider issuing a request for proposals for clinical trials in FY 1983.	

Dietary Therapy of Inborn Errors of Metabolism. Program Goal: To assess the effect of diet on inborn errors of metabolism, especially those diseases that are amenable to nutritional management. (Fiscal Year 1981, est., $2,035,000)

OBJECTIVE	ACTION	NOTES
8. Sustain existing program.	Evaluate results of research activities to determine new directions.	Continue internal coordination, particularly with research programs on Pregnancy, Birth, and the Infant and on Mental Retardation.

Nutrition and Reproduction. Program Goal: To understand the involvement of nutritional factors such as vitamins and minerals in reproductive processes, the reproductive consequences of low protein diet, and the relationship of food resources to reproduction. (Fiscal Year 1981, est., $677,000)

OBJECTIVE	ACTION	NOTES
9. Sustain existing program.	Review ongoing program activity to identify gaps and new questions.	Coordinate internally with research programs on Fertility and Infertility.

Nutritional Antecedents of Adult Disease. Program Goal: To identify factors responsible for and prevent the development of obesity, insulin resistance, and adipose tissue in both normal and obese children. (Fiscal Year 1981, est., $1,360,000)

OBJECTIVE	ACTION	NOTES
10. Sustain existing program.	Monitor existing research activity to determine need for possible expansion.	

Nutritional Aspects of Gastrointestinal Development. Program Goal: To understand the process of cellular differentiation and its relationship to functional development of the intestine and to understand and develop methods for nutritional management of digestive and absorptive disorders in human infants, children, and adolescents. (Fiscal Year 1981, est., $1,396,000)

OBJECTIVE	ACTION	NOTES
11. Increase emphasis on development of new methodologies and basic research needed to advance the field.	Use staff programming to develop studies on cell culture and tissue culture techniques for the study of developmental processes of the gastrointestinal tract. Increase programming efforts to stimulate basic studies on the processes of cellular proliferation, differentiation, and migration as well as increased research on the immune function of the developing intestine.	Coordinate with the NIADDK and NIAID.
12. Expand studies on the distribution of digestive capabilities among populations.	Expand current programmatic effort to stimulate studies on the distribution of intestinal enzyme activity among individuals and the relationship of the distribution to long-term food exposure.	The NICHD has initiated efforts in this area. One contract has been awarded and staff is expanding programming activity.
13. Initiate new studies on the role of colostrum, human milk formulas, and weaning foods as stimulators of gastrointestinal development and function.	Stimulate field by workshop proposed for spring of 1982; include as part of new program announcement in nutrition.	

Nutrition and Development. Program Goal: To better understand: (a) the role of nutrition as a potentiating factor in brain development; (b) the effect of nutritional deficit and excesses in physical growth and maturation; and (c) the effects of non-nutritional food components on growth, development, and health of children. (Fiscal Year 1981, est., $3,592,000)

OBJECTIVE	ACTION	NOTES
14. Evaluate growth rate for optimal physical and functional development.	Identify data for analysis from existing studies such as Guatemala and Bogota; identify areas for study.	

15. Identify effects of chronic and systemic diseases, nutritional imbalance, and(or) hunger on physical growth and mental or motor development.	Develop a program announcement.	Coordinate activities in relation to U.S.-Japan and U.S.-India programs.

Cultural and Behavioral Aspects of Nutrition. Program Goal: To understand the influence of nutritional individuality and cultural and behavioral factors on diet, taste development, food avoidances, and food preferences. (Fiscal Year 1981, est., $1,460,000)

OBJECTIVE	ACTION	NOTES
16. Determine the impact of environmental variables on nutrient requirements.	Plan a methodological workshop involving nutritional scientists, anthropologists, clinicians, and behavioral scientists.	Explore possible establishment of an appropriate initial review group for those aspects of research involving nutritional behavior and anthropology.

Assessment of Nutritional Status. Program Goal: To develop new methods to assess nutritional status focusing on methodologies that are noninvasive and pose the least possible risk to the individual while being both precise and convenient. (Fiscal Year 1981, est., $577,000)

OBJECTIVE	ACTION	NOTES
17. Identify markers of nutritional status as related to: pregnancy and lactation, postpartum or postlactation physiological adjustments, the first year of life, and growth spurt.	Develop a program announcement.	Work in conjunction with Nutrition Coordinating Committee which plans to hold a workshop on the subject in 1981.

Adolescence and Nutrition. Program Goal: To identify the nutritional needs that occur during this period of profound transformation. (Fiscal Year 1981, est., $454,000)

OBJECTIVE	ACTION	NOTES
18. Identify nutritional requirements during the growth spurt.	Increase programming activity to stimulate field.	
19. Determine nutritional needs of pregnant adolescents.	Develop program announcement.	Coordinate internally with research programs on Pregnancy, Birth, and the Infant.
20. Study factors that contribute to food selection during adolescence.	Use results of 1979 NICHD conference titled "Nutrition, Behavior, and Life Cycle" as the basis for stimulating this area.	Coordinate internally with research programs on Child and Adolescent Development.

Sudden Infant Death Syndrome

The sudden infant death syndrome (SIDS) has been defined as the sudden death of an infant or young child that is unexpected by history, where a thorough postmortem examination fails to demonstrate an adequate cause of death. It is a perplexing public health problem that occurs worldwide. In the United States, there are approximately 6,000 to 7,500 victims each year. SIDS has become the leading cause of death in infancy after the first month of life. It occurs more frequently in males than in females, and in nonwhites more than in whites. Infants from low-income families, those who may have had recent infections, and premature infants also are more likely to become SIDS victims.

Research on SIDS covers a broad range of concerns and is directed toward understanding the causes and underlying mechanisms of the syndrome. It focuses on the victim, the family, and the environment in which the SIDS infant lived. Efforts are made to identify infants at risk of becoming victims; determine the relationship between high-risk pregnancy, high-risk infancy, and SIDS; and understand the psychological impact of a SIDS event on parents, siblings, and the extended family. The overall objective of research on SIDS is to identify preventive approaches.

The program goal for research on Sudden Infant Death Syndrome is:

> Sudden Infant Death Syndrome (SIDS): To understand the developmental, physiological, and pathological mechanisms that contribute to the sudden and unexpected death of an infant, with a view toward identification of infants at risk for SIDS and the development of preventive approaches. (Recommendations 1 through 3)

Research Plan

Sudden Infant Death Syndrome (SIDS). Program Goal: To understand the developmental, physiological, and pathological mechanisms that contribute to the sudden and unexpected death of an infant with a view toward identification of infants at risk for SIDS and the development of preventive approaches. (Fiscal Year 1981, est., $4,000,000)

OBJECTIVE	ACTION	NOTES
1. Continue efforts to determine underlying causes and mechanisms of sudden infant death.	Monitor existing grant activity; stimulate submission of new grant applications that address hypotheses relative to SIDS program objectives.	
2. Identify risk factors for SIDS.	Complete data collection under NICHD Cooperative Epidemiology Study on SIDS Risk Factors, analyze these data. Design an appropriate prospective study to test the validity of risk factors identified from data analysis. Issue RFPs for sophisticated analysis.	Coordinate with Office of Maternal and Child Health, HSA, and internally with research program on Pregnancy, Birth, and the Infant.
3. Identify behavioral considerations with regard to at risk SIDS infants and families of SIDS victims.	Develop program announcement and identify needed research.	No systematic studies have yet been undertaken concerning the impact of social, cultural, and sexual factors on the grieving process or on coping with the loss of a family member. Lifestyles most likely to contribute to poor pregnancy outcomes, and possibly SIDS, need to be identified. Office of Maternal and Child Health, HSA, SIDS Information and Counseling Centers provide resources for investigations; coordinate efforts with the NIMH.

Congenital Defects

Each year in the United States, 7 percent of all babies are born with or develop mental or physical defects. One fifth of all infants who die by the age of 4 do so because of congenital defects. In addition, a major proportion of miscarried pregnancies are associated with developmental defects.

Congenital defects are defined as structural, functional, and biochemical anomalies that are initiated in the human organism prior to birth or shortly thereafter and cause immediate or delayed abnormality. Causes may be genetic, chromosomal, or environmental and can affect the developing embryo, fetus, or child. Most often developmental defects appear to result from abnormal interactions of genetic and environmental factors. The etiology of 65 to 75 percent of all congenital defects, however, is still unknown.

The Institute encourages research on the causes of congenital defects. Studies of etiologic factors, normal and abnormal basic developmental mechanisms, and clinical entities are emphasized. A combined clinical and biologic approach may lead to a better understanding of the processes resulting in congenital defects.

The program goals for research on Congenital Defects are:

Developmental Genetics: To define mechanisms important to basic and clinical problems in developmental genetics. (Recommendations 1 through 5)

Developmental Biology: To identify the developmental bases underlying normal mammalian differentiation and morphogenesis. (Recommendations 6 through 10)

Teratology: To prevent and ameliorate birth defects due to genetic, environmental, and multifactorial cause. (Recommendations 11 through 16)

Developmental Immunology: To understand the ontogeny of immune defenses in order to prevent infections and immunologic disease important to the maternal-placental-fetal complex, the newborn, and infant. (Recommendations 17 through 20)

Research Plan

Developmental Genetics. Program Goal: To define mechanisms important to basic and clinical problems in developmental genetics. (Fiscal Year 1981, est., $5,434,000).

OBJECTIVE	ACTION	NOTES
1. Identify gene products essential to critical stages of development.	Consider development of a program announcement; use staff programming to develop needed research.	Coordinate internally with research program on Mental Retardation. More knowledge is needed on gene products involved in developmental anomalies with known chromosome (or segment) aberrations.
2. Improve chromosome resolution techniques.	Receive guidance recommendations from experts in field; and include in possible program announcement.	Coordinate internally with research program on Mental Retardation. Studies are needed to facilitate correlation of cytogenetic with biochemical analyses of chromosomes.
3. Conduct diagnostic studies of genetic disorders through fetoscopy.	Assess results of 1981 program announcement on basic and clinical studies of normal development and developmental defects; use staff programming to develop needed research.	This area includes the application of chromosomal analysis to map the normal and abnormal human genome.
4. Conduct clinical and basic genetic studies on skeletal dysplasias and limb development.	Stimulate research on genetic aspects of limb development through possible program announcement on normal and abnormal limb development.	Coordinate with the NIADDK. Scope of research should include family, twin, and population genetic studies to identify frequency and action of mutant genes, and to separate genetic from environmental causes of abnormal development.

5. Study fundamental genetic mechanisms underlying normal development and genetic disorders; determine the developmental timing of genes.	Assess results of 1981 program announcement which emphasizes mammalian genetics and recommendations from 1981 NICHD cytogenetics conference. Stimulate studies in areas identified for emphasis.	Coordinate with the NIGMS and internally with research program on Mental Retardation. Studies are needed on genetic regulatory mechanisms including characterization of gene structure, transcription, ribonucleic acid processing, and translation.

Developmental Biology. Program Goal: To identify the developmental bases underlying normal mammalian differentiation and morphogenesis. (Fiscal Year 1981, est., $6,880,000)

OBJECTIVE	ACTION	NOTES
6. Study central nervous system development and elucidate hormonal influences on brain development.	Use staff programming to encourage research activity.	Coordinate with the NINCDS and internally with research programs on Nutrition and Mental Retardation.
7. Conduct limb development studies.	Assess existing program; encourage research through possible program announcement. Plan a conference to strengthen genetic and developmental biology cross-fertilization.	Studies are needed on the formation of limb bud, myogenesis, chondrogenesis, and inductive influence of neurons.
8. Study cytoplasmic substances in early development.	Use staff programming to encourage research activity.	Coordinate internally with research programs on Fertility and Infertility and Mental Retardation.
9. Expand studies on pattern formation.	Plan a conference to receive guidance recommendations.	The field of pattern formation needs stimulation because of its importance to human development.
10. Study fundamental processes underlying mammalian development.	Encourage studies on mammalian development. Maintain current efforts in non-mammalian studies.	Coordinate with the NIGMS in area of non-mammalian development.

Teratology. Program Goal: To prevent and ameliorate birth defects due to genetic, environmental, and multifactorial cause. (Fiscal Year 1981, est., $1,917,000)

OBJECTIVE	ACTION	NOTES
11. Develop animal models and culture bioassay models for studies of malformations.	Staff programming will be continued in this rapidly expanding field. Progress will be monitored for application to developmental problems.	
12. Study metabolism, excretion, and deposition of teratogens during development.	Emphasis will be given to those agents that are known or suspected teratogens and will focus on effects on early development. Metabolism will be emphasized in searching for mechanisms of teratogenesis that will lead to studies at the cellular and molecular levels of development.	Coordinate through NICHD Work Group on Genetics and Teratology; coordinate with the NIEHS.
13. Determine basic mechanisms of action of teratogens (gene-environmental effects) and identify genetic differences in drug metabolism.	Assess existing program; use staff programming to identify needed areas for study.	Coordinate with the NIGMS, NIEHS, CDC, and the NICHD Work Group on Genetics and Teratology. Genetics differences between strains and between species may alter the capability of organisms to transport or metabolize teratogens.
14. Evaluate ultrasound exposure during embryonic development and study other environmental influences such as nutrition, maternal metabolic imbalances, ionizing radiation and thermal variations as etiological factors in the cause of birth defects.	Assess existing program particularly with reference to work that emphasizes ultrasound exposure. Also assess maternal nutrition, diabetic pregnancies, radiation, and heat sensitive systems.	Coordinate activities with the FDA and NCI and internally with research programs on Pregnancy, Birth, and the Infant, and Nutrition.
15. Conduct studies on limb bud development and limb malformations.	Encourage research through possible program announcement. Plan a conference to strengthen genetic and developmental biology cross-fertilization.	Coordinate with the NIADDK. The limb is especially sensitive to teratogenic influences. Studies of the underlying teratogenic mechanisms complement the investigations of limb-bud formation, myogenesis, chondrogenesis, and inductive influence of neurons in limb development and the studies of skeletal dysplasias.

16. Conduct biochemical and physiological studies in behavioral teratology.	Use staff programming to develop this research area. Biochemical or physiological studies associated with the functional component are of particular interest.	Coordinate internally with research program on Mental Retardation.

Developmental Immunology. Program Goal: To understand the ontogeny of immune defenses in order to prevent infections and immunologic disease important to the maternal-placental-fetal complex, the newborn, and infant. (Fiscal Year 1981, est., $4,429,000)

OBJECTIVE	ACTION	NOTES
17. Conduct basic studies on ontogeny of immunity.	Assess existing program. The May 1976 NICHD conference, "Development of Host Defenses," focused on the research needs and has provided stimulus to program growth.	Coordinate with the NIAID. The fetal and newborn immunologic defenses must combat an environment of foreign proteins capable of causing allergic conditions, drugs that produce adverse reactions, toxins that affect developmental processes, and infectious agents capable of producing disease and malformations.
18. Study newborn infections and immunologic vulnerability.	This area is closely aligned with studies in ontogeny but may require the development of an announcement in the second year to focus efforts.	Coordinate internally with research program on Pregnancy, Birth, and the Infant. Assess findings of NICHD/NIAID Conference on Maternal Infection, 1981, to identify new research questions.
19. Conduct research on the immunology of breast milk.	Staff programming based on the 1979 NICHD conference on "Immunology of Breast Milk" will be used to advance this research area toward specific goals.	Collaborate internally with research program on Nutrition.
20. Study maternal-fetal immunologic interactions.	Staff programming will be used to identify areas for study based upon the 1981 international conference on reproductive immunology.	The means by which a genetically non-identical fetus is tolerated immunologically by the mother are not adequately understood. It is also essential to understand the mechanisms that control passage of maternal serum proteins and other substances across the placenta.

Mental Retardation

There are about 6.6 million retarded Americans and an estimated 20 to 25 million people in families in which there is a mentally retarded person. Originating in the developmental periods and extending throughout the lifespan, mental retardation exacts a heavy toll on the retarded, their families, and the national resources. Current evidence indicates that the causes of mental retardation are biological, psychological, and social, and can occur in combination in a single individual. The more severe cases are associated with organic defects. Genetic factors, metabolic disorders, and prematurity or other disturbances during pregnancy are a few of its determinants, but infection or injury at birth or in early childhood may also underlie the more severe forms. The milder forms of mental retardation constitute the largest number of cases and are concentrated in families characterized by low income, poor education, and disadvantaged life circumstances.

Although 200 factors, acting either alone or in various combinations, have been identified or suspected as causative agents, little is known concerning the mechanisms by which developmental perturbations result in mental deficiency. Mental retardation research is directed toward: isolating particular factors that can cause abnormal brain maturation; identifying direct and indirect social, economic, and cultural influences on the occurrence of mental retardation; and finding the means to ameliorate the condition of those who are affected.

The program goals for research on Mental Retardation are:

Genetics/Down Syndrome: To understand the biological and biochemical processes of genetic disorders and their developmental consequences. (Recommendations 1 through 5)

Early Diagnostic and Intervention Studies of High-Risk Infancy: To develop methods for (1) early detection of infants with a high degree of risk for becoming mentally retarded; and (2) early intervention with infants at risk to prevent or ameliorate mental retardation. (Recommendations 6 and 7)

Amelioration and Rehabilitation: To develop new knowledge on methods of care, training, and treatment for the purpose of enabling the retarded person to effect his/her optimal adjustment to community life. (Recommendations 8 through 11)

Developmental Neurology: To understand the developmental neurological processes as they relate to mental retardation. (Recommendation 12)

Behavioral Teratology: To elucidate the role of teratogenic agents as causes of mental retardation. (Recommendation 13)

Blood-brain Barrier Mechanisms: To understand the mechanisms of the blood-brain barrier as they relate to mental retardation. (Recommendation 14)

Psychobiological Maturation: To understand the fundamental processes of psychobiological maturation in relation to mental retardation. (Recommendation 15)

Research Plan

Genetics/Down Syndrome. Program Goal: To understand the biological and biochemical processes of genetic disorders and their developmental consequences. (Fiscal Year 1981, est., $3,992,000)

OBJECTIVE	ACTION	NOTES
1. Study the fundamental processes involved in nondisjunction as a cause of Down syndrome.	Complete contract development of the mouse model as a resource for study of trisomy 21.	Two of the three genes responsible for Down syndrome and located on human chromosome 21 have been "mapped" on mouse chromosome. The third gene appears to be on mouse chromosome 16 also.
	Upon completion, develop an announcement indicating availability of the mouse model and provide for its dissemination to investigators.	Provide advance notice to the NIGMS and NINCDS. Coordinate with the NICHD Office of Research Reporting for press release advisory to consumer special interest groups.

2. Elucidate the causes and concomitants of the Fragile X syndrome.	Use staff programming to initiate and conduct epidemiological studies to define the phenotype of the Fragile X syndrome.	Fragile X syndrome is second only to Down syndrome in the frequency of genetically determined cause of mental retardation. There is a high incidence of mild mental retardation among the carriers of the Fragile X.
	Initiate studies on optimum tissue culture conditions that would maximize identification of the Fragile X.	Coordinate with the NIGMS.
	Encourage research on methods appropriate for development of prenatal diagnostic techniques for Fragile X.	
3. Achieve fundamental understanding of the basic mechanisms underlying genetic disorders.	Convene experts in cytogenetics in 1981 to provide guidance recommendations.	Coordinate internally with research program on Congenital Defects.
	Advance studies of gene mapping technology by use of somatic cell hybridization.	
	Initiate studies concerned with methods of genome analysis using recombinant DNA techniques.	
	Initiate gene mapping studies using gene linkage.	
	Use staff programming for studies of behavioral genetics in invertebrates and laboratory mammals.	
4. Identify preventive approaches to the newly emerging problem of maternal phenylketonuria (PKU).	Identify research questions and requirements for a multicenter effort. Support with staff programming and monitoring.	Coordinate with the Office of Maternal and Child Health, HSA.
	Study the effects of a low phenylalanine diet prior to and during pregnancy to determine the effects on development of the fetus.	Women with PKU who have matured to normal adulthood with help of early childhood dietary care are now entering their reproductive years. Without preventive intervention, the incidence of PKU will rise to the levels seen during the years before dietary therapy for PKU.

5. Sustain broad program of research concerned with understanding the fundamental processes involved in genetically determined disorders including errors of metabolism.	Use staff programming to sustain basic programs of studies concerned with understanding genetically determined disorders.	Coordinate with the NIGMS.

Early Diagnostic and Intervention Studies of High-Risk Infancy. Program Goal: To develop methods for the (1) early detection of infants with a high degree of risk for becoming mentally retarded; and (2) early intervention with infants at risk to prevent or ameliorate mental retardation. (Fiscal Year 1981, est., $2,474,000)

OBJECTIVE	ACTION	NOTES
6. Conduct studies designed to establish indicators of early risk status in biologically and environmentally vulnerable infants.	Encourage this development in Mental Retardation Research Centers (MRRCs) associated with a University Affiliated Facility (UAF); effect stronger research association with obstetrical and perinatology units related to the MRRC.	Coordinate with Directors of MRRCs, UAFs, and internally with research programs on Child and Adolescent Development, and Pregnancy, Birth, and the Infant.
	Determine risk variables associated with implantation, pregnancy, birth, the neonatorum and early infancy as these relate to risk for later retarded development.	Consider holding a workshop in conjunction with the 1982 meeting of the American Association on Mental Deficiency.
	Initiate studies on early psychobiological maturation with special reference to indicators of risk status.	
7. Conduct studies leading to the development of early methods for intervention with risk infants that either prevent and(or) ameliorate potential mental retardation.	Study different strategies to alter parent (caregiver) transactions with the infant at risk to optimize the infant's cognitive development.	Consult with the Office of Special Education and with the National Institute for Handicapped Research, U.S. Department of Education.
	Investigate methods appropriate to different population groups.	Service activities by physical therapists are rapidly increasing for this area. This activity is moving ahead without adequate scientific basis.

	Study methods of psychomotor stimulation of the infant at risk as these might be employed to facilitate cognitive development and adaptive behavior. Study the benefits of methods of intervention for infants at risk as a function of the age of child at time of intervention and the duration of intervention.	

Amelioration and Rehabilitation. Program Goal: To develop new knowledge on methods of care, training, and treatment for the purpose of enabling the retarded person to effect his/her optimal adjustment to community life. (Fiscal Year 1981, est., $3,216,000)

OBJECTIVE	ACTION	NOTES
8. Study effects of deinstitutionalization and normalization.	Initiate surveys; explore desirability of issuing a collaborative program announcement with appropriate agencies.	Consult with Bureau of Developmental Disabilities, Office of Human Development Services.
9. Study impact of family variables upon the retarded child reared in own home. Include impact of more severely retarded (multiply handicapped) children on the family.	Plan a conference concerned with research on the family and the retarded child.	Involve National Association of Retarded Citizens in planning conference to be one in the Mental Retardation Research Centers series of conferences providing for wide dissemination of new research knowledge.
10. Study the impact of depriving environments upon psychobiological problems of mental retardation.	Use staff programming to develop longitudinal studies on interactions of environmental variables in shaping course of cognitive development.	Coordinate with the NIMH.
11. Study alternative patterns of care.	Use staff to identify research questions in areas including: (a) foster care; (b) intermediate care facilities; (c) community residences; and (d) community attitudes.	

Developmental Neurology. Program Goal: To understand developmental neurological processes as they relate to mental retardation. (Fiscal Year 1981, est., $8,363,000)

OBJECTIVE	ACTION	NOTES
12. Explore neurological development with reference to mental retardation.	Use staff programming to sustain a strong effort. Give attention to research in areas of neurobiology, neuroanatomy, neurochemistry, and neuropharmacology.	The NINCDS emphasizes research in this area; the NICHD enters this area when neurological development is considered in relation to other organ systems.

Behavioral Teratology. Program Goal: To elucidate the role of teratogenic agents as causes of mental retardation. (Fiscal Year 1981, est., $13,000)

OBJECTIVE	ACTION	NOTES
13. Lay foundations for development of improved methods of teratological investigation.	Review and plan a strategy to improve teratological studies using animals for study of effects on higher order cognitive and behavioral variables. Consider a workshop on this topic.	Coordinate internally with research program on Congenital Defects. Uniform and agreed upon standards for animal studies involving study of teratological agents are needed.

Blood-brain Barrier Mechanisms. Program Goal: To understand the mechanisms of the blood-brain barrier as they relate to mental retardation. (Fiscal Year 1981, est., $493,000)

OBJECTIVE	ACTION	NOTES
14. Study regulation and development of blood-brain barrier mechanisms.	Sustain staff programming efforts.	Coordinate with the NINCDS.

Psychobiological Maturation. Program Goal: To understand the fundamental processes of psychobiological maturation in relation to mental retardation. (Fiscal Year 1981, est., $4,345,000)

OBJECTIVE	ACTION	NOTES
15. Study early psychobiological maturation in relation to mental retardation.	Use staff programming to sustain and direct studies as follows: (a) peripheral and central sensory subsystems and physiological strategies of information processing at different maturational stages; (b) developmental elaboration of motor behavior; (c) maturation of synaptic organizations involved in motivational systems; (d) biochemical	Coordinate with the NINCDS and NIMH and internally with research programs on Pregnancy, Birth, and the Infant, and Child and Adolescent Development.

	pharmacology of protection and interneuronal systems of the immature nervous system, and (e) changing pharmacological properties of different synaptic subsystems in vivo and in vitro.	

Child and Adolescent Development

Research on child and adolescent development encompasses the development of human behavior from the perinatal period through infancy, childhood and adolescence, into early maturity. Its major concern is to determine how the interaction of biological, psychological, social, and environmental factors results in normal behavioral development, and to identify those factors that interfere with such development.

Five major areas are subsumed within this program: (1) developmental behavioral biology, including the study of brain-behavior relationships, the biochemical, physiological, and hormonal bases of behavior, sensory-motor processes, and the reciprocal relationship between biological disease states and psychosocial factors; (2) learning and cognitive development, including perception, memory, reasoning, and comprehension; (3) the development of communicative abilities (speech, language, reading); (4) social and affective development, including parent-child relations, family dynamics, peer relations, social learning and assumption of social roles, and the role of temperament and affect; and (5) health-related behaviors, including behavioral aspects of children's adaptation to physical illness, disease, or disability, and the psychosocial factors that lead to health-endangering or health-fostering attitudes and behaviors in children.

Processes and factors specific to each stage of development are studied as well as the behavioral development of children born at biological risk. Research is also focused on learning problems, delayed or impaired speech and language development, and reading disabilities.

The program goals for research on Child and Adolescent Development are:

Developmental Behavioral Biology: To acquire new knowledge on the biological basis of behavioral development. (Recommendations 1 through 5)

Learning and Cognitive Development: To better understand the sequential development of learning and cognitive abilities during infancy, childhood, and adolescence. (Recommendations 6 through 8)

Social and Affective Development: To better understand the process of, and those factors that foster or impede social and affective development in infancy, childhood, and adolescence. (Recommendations 9 through 11)

Development of Communicative Abilities: To understand the factors that facilitate or impede children's acquisition and development of speech, language, and reading. (Recommendations 12 though 14)

Health-Related Behaviors in Childhood and Adolescence: To understand the precursors, concomitants, and sequelae of health- and illness-related behaviors in children. (Recommendations 15 and 16)

Research Plan

Developmental Behavioral Biology. Program Goal: To acquire new knowledge on the biological basis of behavioral development. (Fiscal Year 1981, est., $1,791,000)

OBJECTIVE	ACTION	NOTES
1. Study the genetic basis of behaviors, such as learning, social and cognitive abilities, and temperament, and of behavioral deficits during development.	Expand the present program of support. Increase emphasis on (1) basic animal studies of gene-behavior relationships and (2) genetic basis of learning and reading disabilities (dyslexia).	Coordinate internally with research programs on Pregnancy, Birth, and the Infant, Nutrition, and Mental Retardation.
2. Determine the role of specific hormones, and their interactions, at different stages of the life cycle, in the development of behavior, including behavioral defects.	Expand the present program of support. Increase emphasis on early prenatal and pubertal stages of development. Plan a workshop on the impact of puberty on behavioral development.	

3. Determine the interrelation of brain mechanisms and behavior in the course of development, including hemispheric specialization of function, neural plasticity, and the neural correlates of specific behaviors.	Expand the present program of support. Increase emphasis on the neurophysiological basis of learning cognitive abilities, and language, including learning and reading disabilities. Plan a workshop on electrophysiological correlates of learning, cognition, speech, and reading.	Coordinate with the NINCDS and NIMH and internally with research program on Mental Retardation.
4. Study the effect of prenatal and perinatal factors on behavioral development including the role of intrauterine factors and those that occur postpartem.	Expand scope and level of support through increased staff programing activity. Plan a workshop on perinatal biological factors that lead to delayed or impaired behavioral development, including difficulties in learning, cognitive abilities, and social interaction.	Coordinate internally with research programs on Pregnancy, Birth, and the Infant, and Mental Retardation.
5. Study the role of basic sensory and psychomotor processes in behavioral development.	Expand existing program with emphasis on the human neonate including studies of infants born at risk.	Coordinate with the NINCDS and NEI and internally with research program on Mental Retardation.

Learning and Cognitive Development. Program Goal: To better understand the sequential development of learning and cognitive abilities during infancy, childhood, and adolescence. (Fiscal Year 1981, est., $3,172,000)

OBJECTIVE	ACTION	NOTES
6. Study the development of both simple and complex cognitive abilities during infancy, childhood, and adolescence, including learning, perception, memory, comprehension, and reasoning.	Increase emphasis on learning and cognitive abilities in middle childhood and adolescence, including studies of learning disabilities.	Coordinate internally with research program on Mental Retardation.
7. Study the development of the ability of the infant and the young child to orient to and perceive visual, auditory, tactile, and other perceptual stimuli.	Increase emphasis on perceptual development during the post-infancy stage of childhood.	

8. Study the development of short-term and long-term memory abilities in infancy and childhood.	Encourage additional research on the role of memory processes in learning and communication, including learning disorders, dyslexia, and developmental disabilities.	Coordinate internally with research program on Mental Retardation.

Social and Affective Development. Program Goal: To better understand the process of, and those factors that foster or impede, social and affective development in infancy, childhood, and adolescence. (Fiscal Year 1981, est., $969,000)

OBJECTIVE	ACTION	NOTES
9. Determine the process of socialization of the child within the family, from mother-infant interaction in infancy, through the development of reciprocal social relations with others during childhood, to assumption of adult roles in adolescence.	Expand existing program of support, with increased emphasis on parental interactions with children at risk, social learning, development of prosocial and gender-specific behaviors, and the impact on children of family disruption and differences in family composition.	Coordinate with the NIMH and internally with research programs on Mental Retardation and Population Dynamics.
10. Identify ecological determinants outside the home that affect social development, including relationships with peers and adults, in day-care, school, and neighborhood settings.	Increase emphasis on social learning, prosocial and sex-role development, peer relations, and development during early and late adolescence.	Coordinate with the NIMH and internally with research program on Population Dynamics.
11. Study the relation of affect and temperament to biological, social, and cognitive factors during development.	Expand the existing program of support.	Coordinate with the NIMH.

Development of Communicative Abilities. Program Goal: To understand the factors that facilitate or impede with children's acquisition and development of speech, language, and reading. (Fiscal Year 1981, est., $4,081,000)

OBJECTIVE	ACTION	NOTES
12. Study phonological development, including the nature and role of speech sounds and how they are acquired and used in the course of language development.	Expand existing program of support with increased emphasis on comparative studies of speech development in non-English language users.	

13. Conduct research on the process whereby children learn the use and relationship of words to each other (grammar and syntax), and acquire the ability to understand word meanings (syntax).	Increase emphasis on the relation of language acquisition to learning, the development of cognitive abilities, and social competence. Plan a conference on the interrelations of cognitive and language development.	Coordinate with the NINCDS and NIMH and internally with research program on Mental Retardation.
14. Study the development of reading ability in children, including the nature and causes of reading disability (dyslexia).	Plan an interdisciplinary workshop on present status and future directions for research on dyslexia.	Coordinate with the NINCDS and NIMH.

Health-Related Behaviors in Childhood and Adolescence. Program Goal: To understand the precursors, concomitants, and sequelae of health- and illness-related behaviors in children. (Fiscal Year 1981, est., $2,191,000)

OBJECTIVE	ACTION	NOTES
15. Conduct research on illness-related behaviors and on behavioral aspects of the child's adaptation to physical illness, disease, and disability, both acute and chronic.	Continue and expand current program of research to include family-oriented studies of physically ill and handicapped children, as well as the child's adaptation to physiological growth changes, such as puberty and menstruation.	Coordinate with appropriate NIH institutes and with the NIMH.
16. Study health-related behaviors, including psychosocial factors that lead to attitudes and behaviors in children that either endanger or foster health.	Continue current program of support, with emphasis on studies on the development of preventive health practices.	Coordinate with other NIH and ADAMHA institutes.

Contraceptive Development

Research on contraceptive development focuses on new and improved methods of fertility regulation for men and for women that are safe, effective, inexpensive, reversible, and acceptable. The objective of this research is to develop an array of methods that couples in all population groups can use successfully.

Research activities included in this category are: (1) synthesis and biological evaluation of new compounds that may affect reproductive processes in the male or female; (2) the development of technology for improved administration of contraceptive drugs; (3) the development of improved vaginal and uterine contraceptives based on chemical or physical methods; (4) clinical trials of sex steroids and peptides for suppression of sperm production and the consequent development of chemical contraceptives for men; (5) clinical and toxicological evaluation of long-acting progestin as a female contraceptive; (6) laboratory studies and clinical trials to develop and evaluate antifertility methods based on periodic abstinence; and (7) studies required to clarify mechanisms of action of specific contraceptive drugs.

The program goals for research on Contraceptive Development are:

Drug Development: To develop safe and efficacious drugs for fertility regulation in both sexes. (Recommendations 1 through 6)

Barrier Methods: To develop improved methods of barrier contraception that will contribute to better efficacy and acceptability. (Recommendations 7 and 8)

Drug Delivery Systems: To develop improved methods of drug administration. (Recommendations 9 and 10)

Reagent Supply: To provide support for the development and distribution of reagents critical for studies on reproductive processes. (Recommendation 11)

Natural Family Planning: To conduct research on new approaches to natural family planning and fertility awareness. (Recommendation 12)

Research Plan

Drug Development. Program Goal: To develop safe and efficacious drugs for fertility regulation in both sexes. (Fiscal Year 1981, est., $5,353,000)

OBJECTIVE	ACTION	NOTES
1. Conduct clinical trials on luteinizing hormone releasing hormone (LHRH) analogs.	Conduct animal safety studies and phase I clinical studies.	Projected studies involve safety assessment of LHRH antagonists and new agonists. The Population Council and the Agency for International Development collaborate in safety assessment. Industrial sponsors share in overall costs.
2. Conduct clinical trials on injectable long-lasting progestins.	Initiate a study on efficacy and safety of norethindrone enanthate. Initiate safety studies on new long-acting progestins developed in collaboration with the World Health Organization.	Study is being coordinated with the World Health Organization via cost sharing with the contractor.
3. Conduct clinical trials on the utilization of natural estrogens.	Begin trials in first year of plan.	
4. Continue ongoing synthesis program.	Synthesize potent luteinizing hormone releasing hormone and initiate studies on isolation of folliculostatin.	Explore leads as developed outside of the current contract program.
5. Continue support of synthesis facility.	Synthesize a number of antifertility drugs. Purify quantities of gossypol.	Synthesis facility serves as a resource for overall synthesis effort.

6. Continue support of biological testing facility.	Maintain program on testing of drugs and delivery systems.	Availability of this facility permits extensive interaction with other national and international programs and individuals concerned with drug development.

Barrier Methods. Program Goal: To develop improved methods of barrier contraception that will contribute to better efficacy and acceptability. (Fiscal Year 1981, est., $1,036,000)

OBJECTIVE	ACTION	NOTES
7. Conduct clinical trials on barrier methods.	Study improvement of existing cervical caps. Study efficacy of cervical cap and sponge diaphragm.	Increasing popularity of barrier methods requires the development of better approaches.
8. Continue to study new barrier methods and spermicidal materials.	Initiate studies to assess new spermicides.	Cost sharing with industry is anticipated.

Drug Delivery Systems. Program Goal: To develop improved methods of drug administration. (Clinical projects include required animal safety studies.) (Fiscal Year, est., $1,250,000)

OBJECTIVE	ACTION	NOTES
9. Conduct clinical trials on drug delivery systems.	First through fourth years: Support trial on new delivery system for existing oral contraceptives. First through third years: Support trials on implantable caprolactone delivery system.	The World Health Organization may collaborate on clinical trials outside of the U.S. Industrial participation for phase III efficacy trials is anticipated.
10. Continue support of research on drug delivery systems.	Initiate animal safety studies. Initiate studies on delivery systems for peptides.	Industrial participation through assignment of patent rights will be pursued.

Reagent Supply. Program Goal: To provide support for the development and distribution of reagents critical for studies on reproductive processes. (Fiscal Year 1981, est., $255,000)

OBJECTIVE	ACTION	NOTES
11. Continue support of reagent supply program.	Kits for the radioimmunoassay of monkey luteinizing hormone may be ready for distribution.	This program provides a large segment of the scientific community with reagents that are used in a wide variety of studies.

		The NIADDK and World Health Organization participate in reagent development.

Natural Family Planning. Program Goal: To conduct research on new approaches to natural family planning and fertility awareness. (Fiscal Year 1981, est., $106,000)

OBJECTIVE	ACTION	NOTES
12. Conduct research on natural family planning and fertility awareness.	Develop plans to assess the efficacy of combined fertility awareness and barrier methods.	New studies on natural family planning are dependent upon the development of new, more precise methods to determine the fertile period. Collaboration is anticipated with the World Health Organization.

Contraceptive Evaluation

Research on contraceptive evaluation addresses the safety and efficacy of methods of contraception. Particular emphasis is placed on long-term safety. Efforts are directed toward the identification of health risks associated with various methods, delineation of particular circumstances that increase risks, and clarification of the specific mechanisms by which adverse effects may arise.

Research is undertaken on contraceptive modalities, including steroids, intrauterine devices, male and female sterilization, barrier methods, and spermicides, as well as studies on health effects in specific populations. Oral contraceptives are evaluated to determine their role in the development of cancer and other neoplasia, heart disease, hypertension, and thromboembolic disease, and metabolic, nutritional, and immunologic disorders. Studies are also directed toward the role of the immune system in the development of thromboembolic complications and to evaluating individual variations in pharmacologic response to contraceptive steroids. Studies on intrauterine devices focus on their effects on the occurrence of gynecologic and obstetric disorders, such as pelvic inflammatory disease, vaginal hemorrhage, ectopic pregnancy, and fetal loss. Studies of sterilization seek to determine whether there are serious long-term medical sequelae of sterilization and specifically whether vasectomy increases the risk of cardiovascular disease. Other studies on sterilization seek to clarify factors related to the return of fertility in men and women following reversal of sterilization. Conventional contraceptive methods are evaluated to identify the use-effectiveness of barrier methods and possible adverse effects of spermicides.

The program goals for research on Contraceptive Evaluation are:

Oral Contraceptives: To determine frequencies of major adverse health effects and minor side effects associ-

ated with oral contraceptive use, to elucidate causation and pathogenesis of these medical effects, and to develop measures and methods for prevention and therapy of the clinical entities comprising the medical effects of oral contraceptives. (Recommendations 1 through 5)

Intrauterine Devices (IUDs): To understand the medical effects and mechanism of action of IUDs. (Recommendations 6 through 8)

Male and Female Sterilization: To study the medical effects of sterilization in men and women. (Recommendations 9 through 14)

Barrier Methods: To assess adverse and beneficial effects associated with spermicide use and use-effectiveness. (Recommendations 15 through 17)

All Methods: To study problems relating to various contraceptive methods. (Recommendations 18 and 19)

Research Plan

Oral Contraceptives. Program Goal: To determine frequencies of major adverse health effects and minor side effects associated with oral contraceptive use, to elucidate causation and pathogenesis of these medical effects, and to develop measures and methods for prevention and therapy of the clinical entities comprising the medical effects of oral contraceptives. (Fiscal Year 1981, est., $3,364,000)

OBJECTIVE	ACTION	NOTES
1. Evaluate the effects of oral contraceptives on the occurrence of cancer and other neoplasias.	Continue ongoing work on the role of oral contraceptives in the development of breast, endometrial, and ovarian cancer.	Continue collaboration with the NCI.
2. Continue ongoing studies to assess mechanisms involved in cardiovascular effects of oral contraceptives.	Evaluate the effects of oral contraceptives on lipoprotein patterns in women; continue studies on the possible role of an immune response to steroids in the etiology of pill-induced thromboembolism.	
3. Initiate new studies on mechanisms of adverse cardiovascular effects of oral contraceptives.	Develop studies on lipoprotein patterns and the occurrence of atherosclerosis in monkeys.	

	Compare the metabolism of contraceptive steroids in women who are hypertensive to that in normal women. Evaluate individual differences in plasma steroid levels and the correlation between plasma steroid levels and changes in measures of blood coagulation; also evaluate effects of different steroid formulations on parameters of blood coagulation.	It will be necessary to identify a population of women who develop overt hypertension as a specific and reversible response to oral contraceptives.
4. Continue studies on steroid contraceptives and the epidemiology of adverse cardiovascular effects.	Perform further analyses of data from Walnut Creek Contraceptive Drug Study.	
	Plan a series of workshops to analyze all data on estimates of hypertensive effects of oral contraceptives.	Pool available data from England and the United States.
	Investigate the relationship between oral contraceptive use and the occurrence of subarachnoid hemorrhage; reassess the risk of venous thromboembolism associated with oral contraceptive use.	Employ new diagnostic methods such as I^{125} scanning and Doppler sound effect.
5. Continue studies on metabolic and nutritional effects of steroid contraceptives.	Assess available information on nutritional status of users of oral contraceptives; plan a workshop to focus on possible needs to revise recommended dietary allowances for this population.	Collaborate with the National Academy of Sciences and the American Council on Science and Health.

Intrauterine Devices (IUDs). Program Goal: To understand the medical effects and mechanism of action of IUDs. (Fiscal Year 1981, est., $130,000)

OBJECTIVE	ACTION	NOTES
6. Study the mechanism by which IUDs cause pelvic inflammatory disease.	Develop a program of contract studies.	

7. Evaluate the effects of intrauterine devices and other contraceptive methods on the occurrence of undesired infertility.	Continue ongoing projects.	
8. Determine the mechanism of action of IUDs in humans.	Plan a workshop to focus on the antifertility effects of IUDs.	

Male and Female Sterilization. Program Goal: To study the medical effects of sterilization in men and women. (Fiscal Year 1981, est., $2,734,000)

OBJECTIVE	ACTION	NOTES
9. Identify long-term sequelae of vasectomy in men.	Continue ongoing historical prospective study; monitor results and consider further followup of study subjects.	
10. Evaluate the role of vasectomy in the progression and regression of atherosclerosis in monkeys.	Continue ongoing study.	
11. Determine whether vasectomy increases the risk of myocardial infarction in men.	Continue ongoing case control studies.	
12. Compare the long-term medical sequelae of various techniques of surgical sterilization in women.	Develop a program of prospective contract studies evaluating changes in frequency of irregular bleeding, pain, and subsequent hysterectomy.	
13. Study surgical reversal of sterilization in women and in men.	Develop multicenter collaborative studies to determine the success rate of various techniques and the factors related to failure to restore fertility.	
14. Evaluate reported endocrine sequelae of female sterilization.	Develop clinical studies to confirm preliminary data suggesting lower midluteal phase progesterone in women who have had surgical sterilization.	

Barrier Methods. Program Goal: To assess adverse and beneficial effects associated with spermicide use and use-effectiveness. (Fiscal Year 1981, est., $1,300,000)

OBJECTIVE	ACTION	NOTES
15. Evaluate the finding that spermicide use may be associated with increased risk of congenital defects in offspring.	Develop a program of contract studies.	
16. Study the putative protective effects of barrier contraceptives against venereal diseases.	Develop a program of contract studies.	Coordinate with the CDC.
17. Evaluate the use effectiveness of barrier contraceptives.	Develop a program of contract studies.	Coordinate with the CDC.

All Methods. Program Goal: To study problems relating to various contraceptive methods.

OBJECTIVE	ACTION	NOTES
18. Compare the health benefits and financial and health costs of various contraceptive methods in current practice with each other and with no method, in various populations.	Plan a workshop to identify research questions and methods of analysis; develop a program of contract studies.	
19. Investigate the relationship between birth control practices (especially oral contraceptive use, spermicide use, and vasectomy) and the occurrence of cervical dysplasia and carcinoma in situ.	Develop a program of contract studies.	

Population Dynamics

Research in population dynamics focuses on the causes and consequences of population change. It addresses questions concerned with growth, distribution, and characteristics of populations and the impact of changes in population on the health and well-being of individuals, families, and the population itself.

A major area of research examines the determinants, correlates, and consequences of fertility and fertility-related behavior, including wanted and unwanted childbearing. Among the topics investigated are determinants of choice of methods for regulating fertility, attitudes toward such methods, and the effectiveness with which they are used. Changes in family structure and function, the consequences of childbearing, and the timing and number of children are also studied. Mortality research addresses the changes and differentials in morbidity and mortality.

Currently, immigration accounts for a large proportion of U.S. population growth and may be the most significant factor in changes in the population. Migration research clarifies the processes by which the migrants adapt and assimilate. Questions are also raised concerning the determinants and consequences of movements of population within a country and the characteristics and composition of the population, especially with respect to household and family structure. As a major mechanism through which population affects society, the family mediates the individual's relationship with other social institutions. Studies of family interrelationships can help identify problems of health and well-being.

The program goals for research on Population Dynamics are:

Fertility: To assess the determinants, correlates, and consequences of fertility and fertility-related behavior. (Recommendations 1 through 6)

Mortality: To assess morbidity and mortality from a demographic perspective to better understand trends and differentials. (Recommendations 7 and 8)

Migration and Population Distribution: To understand the basic demographic process of migration in relation to the individual, society, and the health and well-being of both. (Recommendation 9)

Population Characteristics and Change: To assess the changing composition of the U.S. population especially with respect to household and family formation. (Recommendations 10 and 11)

Research Resources: To encourage the development and use of research data sources, measurement, and analytical techniques. (Recommendations 12 through 14)

Basic Science: To better understand basic issues in the areas of population and health. (Recommendations 15 through 17)

Research Plan

Fertility. Program Goal: To assess the determinants, correlates, and consequences of fertility and fertility-related behavior. (Fiscal Year 1981, est., $6,299,000)

OBJECTIVE	ACTION	NOTES
1. Study the effective use of currently available methods of contraception.	Research needs to be broadened to address groups not studied extensively, such as Hispanics, males, unmarried young adults, and those experiencing unwanted pregnancy. Assess results of research program begun in FY 1981.	
2. Study decision-making and consequences involved in the postponement of childbearing.	Continue FY 1981 contract initiative on delayed childbearing; explore future grant and contract initiatives.	
3. Support life-cycle analyses of the causes and consequences of low fertility.	Assess contribution of research to date, determine need for publication; generate new research applications.	Maintain priority on analyses that are specifically related to U.S. population and health issues.

4. Study causes of increases in out-of-wedlock births, consequences for the family, and implications for society.	Identify research questions and develop a program announcement.	Maintain priority on analyses that are specifically related to U.S. population and health issues.
5. Study female labor force participation and its impact upon the family and upon fertility.	Continue time-use initiative and support of National Longitudinal Survey, Department of Labor. Consider conference to determine next program action.	Coordinate internally with research program on Child and Adolescent Development; relate to interests of the NIMH.
6. Study antecedents to teenage fertility.	Assess previous research; consider new grant initiative on antecedents of teenage pregnancy.	Collaborate internally with research programs on Pregnancy, Birth, and the Infant, and Child and Adolescent Development.

Mortality. Program Goal: To assess morbidity and mortality from a demographic perspective to better understand trends and differentials. (Fiscal Year 1981, est., $265,000)

OBJECTIVE	ACTION	NOTES
7. Study sex differences in mortality and morbidity.	Develop area through use of grant mechanism, or program announcement.	Collaborate with the NIA.
8. Study sources of differentials in mortality in the United States.	Develop primarily through grant mechanisms and interagency agreements.	Collaborate with the NIA.

Migration and Population Distribution. Program Goal: To understand the basic demographic process of migration in relation to the individual, society, and the health and well-being of both. (Fiscal Year 1981, est., $1,643,000)

OBJECTIVE	ACTION	NOTES
9. Sustain existing program.	Conduct an assessment of program's future direction. Identify NICHD role with reference to other agencies. Explore collaborative opportunities with other institutes and agencies.	

Population Characteristics and Change. Program Goal: To assess the changing composition of the U.S. population especially with respect to household and family formation. (Fiscal Year 1981, est., $1,597,000)

OBJECTIVE	ACTION	NOTES
10. Study determinants and consequences of various household structures.	Assess results of FY 1981 and FY 1982 contract initiatives before further program actions.	Determine necessary collaborative arrangements for data collection with the Bureau of the Census. Relevance depends upon U.S. health issues and the role of NICHD with respect to other agencies.
11. Study consequences of slowed rate of population growth and changing environmental characteristics.	Develop program announcement.	Coordinate with the NIA.

Research Resources. Program Goal: To encourage the development and use of research data sources, measurement, and analytical techniques. (Fiscal Year 1981, est., $2,266,000)

OBJECTIVE	ACTION	NOTES
12. Conduct analyses of questions of timing with life cycle approaches and time series methods of analysis.	Continue emphasis on investigator initiated grants; consider research contracts on carefully defined questions.	
13. Improve existing and develop new methods of measurement.	Continue emphasis on investigator initiated grants; consider research contracts on carefully defined questions.	
14. Expand data collection activities.	Facilitate data collection and expand usefulness of other data sets. Continue support of bibliographic research.	Continue collaboration with Bureau of the Census and other data-gathering agencies to create and disseminate data tapes for public use.

Basic Science. Program Goal: To better understand basic issues in the areas of population and health. (Fiscal Year 1981, est., $377,000)

OBJECTIVE	ACTION	NOTES
15. Conduct comparative analysis utilizing new data sets.	Assess need to inform research community of the availability of data sets and need for comparative analyses. Continue support of projects to extract early Census data.	Continue collaboration with Bureau of the Census and other data-gathering agencies to create data tapes for public use. Maintain priority on comparative analyses that are most specifically pertinent to U.S. population and health issues.
16. Study decision-making processes regarding fertility, migration, and household structure.	Sustain existing program; synthesize findings of completed projects and disseminate to research community.	Analysis should identify gaps in research and findings and techniques of potential use to other investigators.
17. Study aspects of ethnicity.	Assess the usefulness of available data.	National Longitudinal Survey, Department of Labor, provides source of valuable data on Hispanic populations.

Research Resources

Research Training

Well-trained, talented investigators are the key resource for the advancement of knowledge through research. There is growing evidence, however, that this resource is shrinking. The number of productive, established researchers is decreasing, and younger investigators, especially those with clinical training, are not entering research careers. Factors leading to these trends should be identified, and efforts should be made to reverse them, particularly in research areas supported by the NICHD.

These efforts should include the awarding of training grants and fellowships. The granting of such awards, at predoctoral as well as postdoctoral levels, can recruit young investigators, emphasize interdisciplinary training and collaboration, and develop capabilities in disciplines that require special expertise. For instance, programs in the field of nutrition can be structured to support the training of individuals with degrees in such disciplines as biochemistry, physiology, bioengineering, medical physics, anthropology, and the social sciences.

A different but no less important need is the training of scientists to aid the transfer of knowledge from the research setting to the clinical setting. Training grants that have this purpose are indispensable in the health science community, and NICHD needs are critical in obstetrics and gynecology, perinatology, and endocrinology.

Centers

The NICHD research centers provide ways to support important collaborative interdisciplinary and multidisciplinary research and offer facilities for studying broad and long-range issues and formulating interdisciplinary research

that otherwise might not be possible. The centers mechanism also attracts investigators and trainees in new scientific disciplines and encourages investigators of different disciplinary backgrounds to work together in planning fresh approaches to research objectives.

Equipment

During the last decade, rapid advances in instrumentation technology have paralleled those in research methodology, with the result that many biomedical and behavioral science research laboratories have obsolete equipment. For laboratories to maintain their capability, sensitivity, and reliability, old and worn equipment should be replaced with modern instruments. The identification and quantification of hormones in body fluids and tissues by radioimmunoassay and immunocytochemistry, for example, depend on highly technical procedures and sophisticated instruments. Studies of the isolation, chemical characterization, and synthesis of hormones are similarly dependent. The instruments of these new technologies are critical to the advancement of programs supported by the NICHD.

Animals

The selection and development of appropriate animal models, which have provided insights into the prevention and cure of many human diseases, are necessary for research supported by the NICHD. To develop animal models, breeding colonies with a stable population are necessary. Old world monkeys, especially the macaques, have yielded information on the mechanisms regulating menstrual and reproductive cycles, but they are scarce and expensive. Similar problems are associated with rhesus monkeys and the common chimpanzee. The pygmy chimpanzee Pan paniscus is anatomically, genetically, and immunologically man's closest relative, but it is an endangered and protected species. Because of the costliness of facilities, the scarcity of animals, and the complexity of the technology, a centralized facility is important, especially for breeding nonhuman primates. Well-defined nonhuman primate colonies are also invaluable for nutrition research.

Neurobehavioral disorders that provide a model for disorders associated with human mental retardation have appeared in mutant animals. The study of such mutants can lead to the identification of pathogenetic mechanisms in mental retardation. Similarly, the development of a satisfactory model for the study of fertility and infertility in women would be extremely beneficial.

Other valuable animal models include congeneic and recombinant animals, animals that serve as appropriate models of human congenital abnormalities, and genetically defined obese mice and rats.

Strategy for Continued Evaluation and Planning

Effective evaluation and planning are essential to the achievement of NICHD goals. Throughout its history, the Institute has developed and refined methods for regular review of its research programs and progress. These efforts, which have contributed substantially to the Institute's effectiveness in evaluation and planning, must be continued, expanded, and strengthened.

The Institute's past planning activity has been confined to preparation of annual research plans for inclusion in the overall National Institutes of Health Research Plan and for use in budget preparations. These plans, while useful, have lacked continuity and have not provided measures by which to assess research progress. Moreover, the plans have not been based on comprehensive evaluations of research needs and opportunities.

Until recently, evaluation activities were not formalized. In the past several years, however, evaluation at the NICHD has taken on increasing significance and has involved a greater number of Institute participants. Typical of the Institute's evaluation activities is the program review conducted by the National Advisory Child Health and Human Development Council at each of its quarterly meetings. All Branches of the NICHD make thorough presentations to the Council on their research programs, objectives, and progress.

The completion of the NICHD Five-Year Research Plan signifies the Institute's first successful integration of evaluation and planning efforts. Additionally, it affords the Institute a unique opportunity to inaugurate a systematic, annual program of evaluation and planning.

The Plan is based upon an evaluation project entitled "Development of Objectives and Performance Indicators for

NICHD Programs of Research for Mothers and Children and Population Research" (NICHD-80-305/306). Stage 1 of this evaluation, which was completed in May 1981, resulted in the clarification of program goals and identification of research objectives for each of the 10 program areas. The Institute now plans to initiate Stage 2 of this evaluation. This second stage will be conducted over a 4-year period and will require in-depth analyses similar in scope and content to the Study Group reports prepared for the Five-Year Research Plan.

Stage 3 will be pursued concurrently with Stage 2 and will involve planning for future research by identifying new program objectives and assessing program performance.

The process is scheduled for completion in 1987, which is the last year of the Plan. The current Stage 1 and planned Stage 2 and 3 efforts are responsive to the information needs identified by the Congress, Department of Health and Human Services, Public Health Service, and the National Institutes of Health. Most importantly, the results of these activities will contribute to the effective management of the Institute's research programs and will be utilized in the planning, legislative, budget, and program management functions of the NICHD.

The schedule of program performance evaluations appears on the facing page.

Schedule of Program Performance Evaluations*

Program	Stage 2: Development of Agreed-Upon Evaluation Design or Other Information System — Begin Date	Stage 2: Development of Agreed-Upon Evaluation Design or Other Information System — Complete Date	Stage 3: Production of Program Performance Information in Terms of Agreed-Upon Evaluation Design or Other Information System — Date When Performance Information Will Become Available
Sudden Infant Death Syndrome	12/81	5/82	6/83
Child and Adolescent Development	12/81	5/82	6/83
Population Dynamics	12/81	5/82	6/83
Contraceptive Development	11/82	4/83	5/84
Congenital Defects	11/82	4/83	5/84
Fertility and Infertility	11/82	4/83	5/84
Pregnancy, Birth, and the Infant	10/83	3/84	4/85
Nutrition	10/83	3/84	4/85
Contraceptive Evaluation	10/83	3/84	4/85
Mental Retardation	10/84	3/85	4/86

* Stage 1, "Clarification of Program Goals and Identification of Program Objectives and Performance Indicators," was completed in May 1981.

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Appendix 1

Method of Study

The Five-Year Research Plan for the NICHD was prepared on the basis of an evaluation of its existing program areas. These program areas are: Fertility and Infertility; Pregnancy, Birth, and the Infant; Nutrition; SIDS; Congenital Defects; Mental Retardation; Child and Adolescent Development; Contraceptive Development; Contraceptive Evaluation; and Population Dynamics.

Study Groups that consisted of an outside expert and a health scientist administrator were convened for each of the 10 program areas. Intramural members were added as appropriate. The Study Groups met in February, 1980, with the Steering Committee of the Five-Year Research Plan and were asked to prepare reports on their respective program areas and to answer four questions as follows:

What is the state of the science?

Where are the gaps and opportunities?

What research areas should be pursued in the future?

What resources are necessary?

Upon completion of interim reports in June and July, 1980, each outside expert (Key Consultant) participated in a scientific review of his or her report. These reviews were conducted by the Institute's standing research committees and by groups of ad hoc reviewers. Each document was also reviewed at this time for policy considerations by the Steering Committee. Subsequent to the reviews, Study Groups revised their documents in accordance with changes suggested in the reviews; the revised documents were reviewed and approved by the Steering Committee in October, 1980.

Subsequently, the Steering Committee proceeded to develop an implementation plan for the first year, fiscal year 1983, of the Five-Year Research Plan. The process by which this was done follows.

The recommendations for future research as presented by each Study Group report were examined by Task Forces of the Steering Committee to determine their relevance to the Institute's mission, their relative importance, and whether or not sufficient argument was presented in the Study Group reports for their acceptance. The results of the Task Force deliberations were compared to the existing program of research to identify overlap and gaps. The results of this process were presented to the Steering Committee in the form of decision memoranda which the Steering Committee and staff used to arrive at recommendations for future research in each of the 10 program areas.

Appendix 2

Charge to the Study Groups (February 1980)

The task of each Study Group is to examine the content of research conducted within its program area, consider its relevance to health problems and societal concerns, and identify gaps in knowledge and questions that should be addressed. Utilizing resource material and consultations with other experts in the field, the Study Groups are asked to produce a report. This report is to evaluate the state of the science of that area of research, assess research progress, and recommend future research activities.

These evaluations are intended to provide the essential basic elements for developing the NICHD Five-Year Research Plan.

The core personnel of each Study Group are a Key Consultant, selected from the research community for his or her knowledge and familiarity with NICHD research activities, and a Program Staff Member, selected from the extramural research program administration. As needed, Study Groups are augmented with additional consultants and with staff from the intramural research program.

Each Study Group is asked to address the following questions:

- What progress has been made in research in your program category?
- What important questions remain unresolved?
- What are the gaps in research that should be addressed, or new areas that warrant support?
- In what scientific areas are research investments likely to be most rewarding? What are the areas of greatest opportunity?

- What ongoing research carries a lesser sense of opportunity or urgency?

- What areas of research should be given priority? What do you recommend should be pursued in the immediate future?

- What resources are needed to implement your recommendations?

The general schedule of activity is as follows:

Study Groups' Interim Reports Preparation (February-July 1980)

Utilizing resource material, consultations with other experts in the field, and their deliberations, each of the Study Groups shall develop a report based upon a state-of-the-science assessment of the field of research, program objective, basic data on the health problems relating to that area of research, and recommendations for future research activities.

Study Groups' Interim Reports Review Meeting (July-August 1980)

The reports will be reviewed by the Steering Committee and the Institute's in-house review committees; the former review for relevance to Institute mission, relation to health problems, and the degree to which the original "charge" has been fulfilled, and the latter for science and substance.

It is expected that the Key Consultant for each of the Study Groups will attend the review committee meetings at which his or her group's report is reviewed.

Study Groups' Draft Final Reports Preparation (August-September 1980)

Each of the Study Groups, utilizing the comments and recommendations of the reviews, will prepare a final report.

Draft Final Report Review (October 1980)

The draft final reports will be submitted to the Steering Committee. Upon final acceptance, they will be prepared for publication. At this time, they will also be used by the Steering Committee and extramural staff as bases for future research plans. (See "Procedure for Development of a Research Plan.")

Appendix 3

Plan for Review and Lists of Reviewers (June 1980)

The procedures for the development of the Five-Year Research Plan call for an interim review of the 10 Study Group reports for both scientific content and policy considerations.

The scientific review of the reports related to maternal and child health will be conducted by Institute standing review committees; the review of the population research papers will be conducted by ad hoc reviewers.

Specifically, the Maternal and Child Health Research Committee (MCHRC) will review the following reports: Pregnancy, Birth, and the Infant; Sudden Infant Death Syndrome; Nutrition; Mental Retardation; Congenital Defects; and Child and Adolescent Development. The Mental Retardation Research Committee (MRRC) will review the Mental Retardation report, Congenital Defects report, and Child and Adolescent Development report. The MCHRC review session will take place on Tuesday afternoon, July 29, and from 9:00 a.m. to 12:00 noon on Wednesday, July 30, 1980. The MRRC review session is scheduled for Tuesday, July 29 from 9:00 a.m. to 12:00 noon.

Ad hoc reviewers have been selected for each of the four reports on population research. Their reviews are scheduled as follows: Contraceptive Development--June 16, 1980; Contraceptive Evaluation--mail review; Population Dynamics--June 24, 1980; and Fertility and Infertility--August 7, 1980.

Principal reviewers will be asked to prepare written comments for discussion at the scientific review sessions. These individuals will receive advance copies of the reports. They will prepare written comments, forward them to the Project Director, who, in turn, will forward them to the

Key Consultants of the Study Groups. The Key Consultant will be present at the scientific review sessions to respond to questions raised by the reviewers.

A policy review will be conducted by the Steering Committee on July 31, 1980. Principal reviewers will be designated to review and comment on the respective Study Group reports. Guidelines for review of the interim reports have been developed to facilitate the scientific and policy reviews as follows:

Guidelines For Scientific Review

These guidelines have been developed to assist members of the Mental Retardation and Maternal and Child Health Research Committees as well as ad hoc committees in areas of population research in the review of Study Group interim reports.

Each interim report should be reviewed with reference to the following:

- Have the authors defined the research addressed by the report? Do the reviewers consider the definition adequate? If the definition is inadequate, why?
- Does the report reflect our current state of knowledge?
- Does the report reflect evaluations, opinions, and recommendations of others not directly participating in the NICHD planning effort?
- Are the directions for future research realistic? Do they identify areas of significant opportunity and(or) need?
- Have all relevant components and needs for future research been identified? Are they explained and discussed sufficiently?
- Has the report identified needed resources and their availability and accessibility?
- Is the report written in a style readily understandable by the educated lay person?
- Have the authors ranked future research needs in order of priority? Are you in agreement with that ranking? If not, why not?

Guidelines for Policy Review

In addition to scientific review that will be conducted by standing and ad hoc committees of the Institute, Study Group interim reports will be reviewed by the Steering Committee for the Five-Year Research Plan.

The Steering Committee review addresses the following questions:

- Does the Study Group meet the charge?
- To what extent does the report relate (or not relate) to the Institute's mission?
- Does the report identify research objectives and place them in order of priority?
- Does the report identify needed resources?
- Do the authors consider and utilize data on the incidence and prevalence of health problems that fall within the scope of the subject program plan category?

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Appendix 4

Procedure for the Development of a Research Plan (October 1980)

I. RATIONALE

In order to fulfill the objective of the NICHD five-year planning effort, it is necessary to engage in a procedure that will translate results of the 10 Study Group reports into a research plan to guide the Institute's activities. The 10 Study Group reports represent evaluations of the state of the science in NICHD areas of research and also identify future needs for research. From these evaluations, the Steering Committee must now develop a staged (or phased) plan of recommendations for future research.

The research plan that will be developed should serve not only as a basis for yearly evaluations, but also as a means by which the Institute can measure its performance in achieving research objectives.

II. PROCEDURE

Step 1.

For each of the 10 program areas, a workbook will be assembled, including: (1) a listing of all current research grants and contracts within the program area with dollars and numbers of projects identified, (2) a narrative description of the existing research program, (3) an index to recommendations contained within the Study Group report and copies of pages from the report that show the recommendations in full text, and (4) for each recommendation, a worksheet that lists the following questions: Is the recommendation within the NICHD mission?; What is its importance to the

NICHD?; Should the recommendation be modified and if so, how?; and What is necessary for its implementation?

Step 2.

Task Forces of the Steering Committee will be formed and given the workbooks to use in comparing the program descriptions and research portfolios with the recommendations for research derived from the appropriate Study Group reports. The objective of this analysis is to answer these questions:

1. How does the existing program relate to the recommendations of the Study Group?

2. Do the recommendations relate to the Institute's mission or are they shared with or the responsibility of another Institute or agency?

3. What recommendations should be pursued in a first year (Phase I) of a five-year research plan? What recommendations should be reviewed in a year for possible future implementation?

4. Looking at the Institute's current research activity in light of the recommendations, where should there be increased activity, de-emphasis, or new activity?

5. Where new or accelerated activity is recommended, what are the resources needed and what are feasible objectives? What mechanisms are suggested to achieve the objectives, such as RFA, RFP, or workshops?

Step 3.

When the Task Force has completed its work, the results of its deliberations will be provided to the appropriate Branch or Section Chief (who in all instances is also the person who served as Program Staff Member on the Study Group). The Branch or Section Chief, with his or her staff, is to develop draft Implementation Plans as follows:

1. Overall program objectives are to be identified and each recommendation of immediate and future importance is to be placed appropriately within an objective.

2. Total dollars and numbers of projects are to be identified for each objective for fiscal year 1980.

3. Total dollars and numbers of projects are to be identified for each recommendation given an immediate priority for fiscal year 1980.

4. For each recommendation given an immediate priority, program staff is to identify a method for its implementation such as a research workshop or a program announcement.

5. Where appropriate, collaborative and coordinative arrangements are to be identified.

The results of the Branch or Section staff deliberations will be arrayed on an Implementation Plan Worksheet in the following format:

Program Objective: _____ Fiscal Year 1980 data: _____

Recommendation	Plan of Implementation for First Year	Collaborative and Coordinative Arrangements	Remarks	Steering Committee Decision

Step 4.

Draft Implementation Plans will be presented separately to the Steering Committee by the appropriate Branch or Section. The Steering Committee will discuss each plan with the Branch or Section staff and reach decisions regarding recommended directions for research for the first year phase of the Plan.

Step 5.

The decisions of the Steering Committee will be compiled into an overall Research Plan and will be presented for review and comment to the Director, NICHD, and the Subcommittee on Planning and Evaluation, National Advisory Child Health and Human Development Council.

III. OUTCOME

It is expected that this procedure will result in the development of a Five-Year Research Plan representing: first, a series of decisions on the directions for the

Institute's research, realistically concentrating on the first year of the Plan's activities but ideally giving a framework for a five-year program; and second, a basis upon which the Institute can perform yearly evaluations on the achievement or progress toward the performance objectives.

IV. TIMETABLE

October 1980--Program descriptions and portfolio of current research activity to be developed and workbooks to be assembled; Steering Committee Task Forces to be constituted.

November 1980-January 1981--Task Forces to deliberate and develop reports for Branch or Section staff action.

January-April 1981--Branch and Section staff complete proposed Implementation plans; present plans to Steering Committee for deliberation and action; Steering Committee decisions used to compile Research Plan.

May 1981--Director, NICHD, and Subcommittee on Planning and Evaluation review Research Plan and comment to Steering Committee.

October 1981--Volume I, including the Research Plan, and Volume II, including the 10 Study Group reports are presented to the Director, NICHD and to the National Advisory Child Health and Human Development Council.

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